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BIOTECHNOLOGY AND AGRICULTURE

HEARINGS
BEFORE THE
SUBCOMMITTEE ON
INVESTIGATIONS AND OVERSIGHT
OF THE
COMMITTEE ON
SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
NINETY-NINTH CONGRESS
FIRST SESSION

APRIL 16, 17, 1985

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BIOTECHNOLOGY AND AGRICULTURE

TUESDAY, APRIL 16, 1985

House of Representatives,
Committee on Science And Technology,
Subcommittee on Investigations and Oversight,
Washington, DC.

The subcommittee met, pursuant to call, at 1 p.m., in room 2318, Rayburn House Office Building, Hon. Harold Volkmer (chairman of the subcommittee) presiding.

Mr. Brown. The committee will be in order.

The chairman apologizes for having to relinquish the chair to me because of physical difficulties that he is having, laryngitis.

It is a pleasure for me to be here this afternoon as a member of this subcommittee and have the benefit of this excellent panel this afternoon.

I have a short opening statement which, if you will bear with me, I will read to the record.

We welcome you to the first of 2 days of hearings on biotechnology and agriculture.

Biotechnology, when applied to agriculture, offers both tremendous promise and potential problems. In plant agriculture, scientists have been conducting research aimed at improving specific plant characteristics such as insect resistance and photosynthetic efficiency, as well as research aimed at producing natural insecticides or disease suppressant microorganisms. In animal agriculture, biotechnology offers the possibility of control of animal diseases, improvement of breeds, and enhanced animal nutrition and growth.

But the very benefits which biotechnology may offer also bring problems.

In 1983, for example, surplus milk production in the United States cost taxpayers approximately $2.6 billion in price supports. That same year, scientists at Cornell University were experimenting with genetically engineered bovine growth hormone that could increase milk production even more. By 1990 these same scientists believe that milk production can be increased by over 20 percent.

What we really need is a hormone that will produce just as much milk as the people will drink.

These facts raise a very important question: How can U.S. farm policy be adapted to provide for these advances brought about by biotechnology research, without creating major disruptions in an already shaky farm economy?

Over the next 2 days, we will seek answers to these and other important policy questions in the area of genetic engineering for agriculture. To help provide answers, we will hear from witnesses representing key Federal agencies, universities, industry, and public interest organizations. The hearings will focus on four issues: first, recent advances in biotechnology research; second, joint research projects between land-grant universities and industry; third, the impact of regulation on the future of biotechnology; and, fourth, the impact of genetic engineering on agriculture policy.

Now I would like to recognize Mr. Morrison for any statement that he might have this morning on behalf of the minority.

Mr. MORRISON. Thank you, Mr. Chairman. Mr. Packard is not able to be with us. I will not read his statement. We would ask that it be made a part of the record.

Mr. BROWN. Without objection, so ordered.

[The prepared statement of Mr. Packard follows:]

PREPARED STATEMENT OF HON. RON PACKARD

Mr. CHAIRMAN. The hearings we are holding today and tomorrow bring to further discussion the issue of biotechnology. Biotechnology offers a great deal of hope for solving many of the problems our world faces. One of the first areas biotechnology will significantly impact is agriculture, where the applications promise to produce new varieties of crops which are disease-resistant and greatly increase yields, and animals production.

The United States currently leads the world in biotechnology. We must design a policy which will ensure that the United States maintains this lead. However, in designing such a policy, we must protect the health and well-being of individuals and our environment.

Chief among the issues to be pursued during these hearings is the question of how biotechnological advances will affect and shape our Nation's farm policy. I believe these hearings will provide us some of the answers about what changes must be made in U.S. farm policy to ensure a healthy farm economy and a continued low-cost food supply. The American farmer, and particularly the family and mid-sized farmer, must implement and utilize the advantages from biotechnological research if they are to remain competitive in the world market place.

I look forward to the testimony of our expert witnesses.

Mr. MORRISON. I would comment only that these hearings are going to be very important to a number of us, particularly those of us who also have membership on the Agriculture Committee. We investigated export market opportunities this morning, Mr. Chairman. We found that America has a long way to go to truly be competitive, and our only real edge is in the area of the application of high technology. And the presentations during these hearings, I think, will be most significant in the formation of farm policy that matches these new opportunities.

Mr. Packard, I have asked that your statement, which was spectacular, be made a part of the record.

Mr. BROWN. It was a brilliant statement, and I will ask Mr. Packard if he would like to supplement it in any way at this time.

Mr. PACKARD. I have no need to read it. It is such a profound statement that I think most of you will read it very carefully anyway. So, I will simply allow the hearing to go on, and I am looking forward to the witnesses' testimony.

Mr. BROWN. Thank you, Mr. Packard.

I am very grateful to this distinguished panel of witnesses, all of whom I recognize to be preeminent in their field, for being here this morning. I will recognize Dr. Bentley at this time to proceed as he sees fit and to introduce the other witnesses in whatever appropriate order he wishes. Of course, the full text of all of your statements will be included in the record at this point. Dr. Bentley?

STATEMENTS OF ORVILLE G. BENTLEY, ASSISTANT SECRETARY, SCIENCE AND EDUCATION, U.S. DEPARTMENT OF AGRICULTURE; TERRY KINNEY, ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE; J. PATRICK JORDAN, ADMINISTRATOR, COOPERATIVE STATE RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY G. GERALD STILL, ARS

Mr. BENTLEY. Thank you, sir.

Chairman Volkmer, I am sorry that you have trouble with your voice, but it is a pleasure to be before Mr. Brown again because we certainly have had many opportunities to appear at hearings when he chaired the meetings and other members of the committee.

We are pleased to be here this afternoon. I have with me on this panel three members of our staff: on my left, your right, Dr. Jordan of CSRS; on my right, Mr. Kinney, the Administrator for ARS; and Dr. Still is on the ARS staff. Both of these people will be prepared to answer questions and deal with some of the issues that you bring up.

I thought with the chairman's permission that we would proceed, that I would make a statement first, and then would leave the questions, such questions as you may wish to direct to the panel and for any comments that they may wish to make to supplement my remarks.

I want to begin by saying that these are exciting times in the agricultural sciences. And you have made reference to that in the opening comments by members of the committee. There are new technologies that hold great promise for finding solutions to some of the more difficult problems that have plagued the American farmer for many years and for providing innovative ways to reduce the costs of farming in the future. I hasten to add that these new technologies will provide research scientists working in agriculture the tools to make further contributions to this Nation's important biomedical research programs as well as in agriculture.

You have asked us today to describe the USDA's biotechnology research programs, to provide insights in current advances in biotechnology research, and to discuss the direction future research may take.

First let me begin by making some comments about the definition for biotechnology. It is broadly defined as the use of living organisms or their components in agriculture, food, and other industrial process. And it is not something new to the USDA and to the agricultural research community. Agriculture has a long history of improving food, feed, and fiber through the introduction and the improvement of new plants, animals, and microorganisms. Indeed, virtually all our crop plants and animals in use today were developed in this manner.

Biotechnology research in agriculture today centers about our new capabilities in molecular biology, and most especially those involving recombinant DNA methodologies. These new approaches to participate directly at the molecular level in the design of the heritable information in our view is vastly important to agricultural research.

We are at one of those rare pivotal points in human history when new tools are developed and honed that are capable of changing markedly the rate at which advances in productivity are achieved. We are applying tissue, cellular and molecular level technologies toward achieving whole animal, plant, and microbial improvements.

To turn for a moment to recombinant DNA research, I want to note that USDA scientists were among the first participants in meetings, conferences, and discussions where DNA research policy was developed. In 1976, a committee was formed in the USDA to coordinate research policies among the various agencies in the department, and between USDA, the National Institutes of Health, and the National Science Foundation. This committee, authorized by the Secretary of Agriculture, is the Agriculture Recombinant DNA Research Committee, or ARRC. In recognition of the need for uniform guidelines, the Department adopted the NIH guidelines for research involving DNA molecules for coordinating interagency research review. This committee also established an internal policy requiring compliance with these guidelines as a condition for receiving funds for research.

Dr. Edgar Kendrick, Administrator of the USDA's Office of Grants and Program Systems, will appear before this subcommittee tomorrow afternoon to address the relationship between biotechnology, regulation and the needs of the agricultural industry. He will also address the public comments submitted to the Department since the "Proposal"—quote—"for Coordinated Framework for regulation of Biotechnology" that appeared in the December 31, 1984, Federal Register.

The USDA has continued to place increased emphasis on biotechnology research to benefit agriculture, forestry, natural resources, and the related industrial processes. Our direct commitment in terms of funding this fiscal year totals $75.1 million to both USDA laboratories and those of universities; $20 million of this results from the fiscal year 1985 increase in the competitive research grants. In addition, more than $30 million will be expended from non-Federal sources by the State agricultural experiment stations. This program, of course, extends to a vast array of biologics, plants, animals, and microorganisms.

The current advances are indeed encouraging. From growth rates and synthesis of new compounds in animal and plant systems, to new progress in recognizing genetic codes and their replication systems, and in the isolation of valuable genomic sequences in major crops, these are but a few of the major advances that have already occurred this year.

Certainly the advances in diagnostics include molecular probes—including molecular probes are providing wholly new sets of tools and techniques. Indeed, this one aspect alone, that is, new tools and techniques, is in my view most striking, for it places modern biology capabilities in the hands of each investigator, and in this manner will substantially increase total research efficiency.

The development of research on the applications of biotechnology in agriculture is an integrative process in the USDA and the State agricultural experiment stations. We both generate and draw upon a wide range of biological science disciplines and expertise. From the very synthesis of the early molecular recognition and replication, to elaborate messenger and synthesis systems, to cellular, tissue, and living biota, these exciting exploration are under way. That is, as research unfolds in the basic sciences—genetics, biochemistry, physiology, and microbiology—their application to research in crops, livestock, soils, pest and disease control, and diagnostic testing opens new opportunities for progress.

On the more fundamental side, scientists are developing techniques for recognizing the genetic code for a broad range of desirable traits such as disease and pest tolerance in plants, hardiness under environmental stress, increased yields, the production of biologics for disease control in animals and plants, and animal hormone production using genetically modified bacteria.

To cite an example that illustrates linkages of new technology, it was reported just last week, it comes from scientists at Texas Tech University at Lubbock, where they reported that they were able to produce a whole plant from cell cultures of cotton.

The university is now exploring the ways to develop plants from saltbush, a forage crop which can be grown in arid lands. At other agricultural laboratories, scientists have produced whole plants from the cells of tobacco, oats, wheat, sorghum, and corn.

Such work will allow the agricultural scientists to develop plants which are drought resistant, saline resistant, and even disease resistant. With dwindling water supplies in some parts of the United States, and with a growing concern for the environment, this type of research is absolutely critical.

On March 18, the USDA announced that results from testing of a genetically engineered antigen could help develop a vaccine against coccidiosis, a disease which costs the poultry industry about $300 million each year.

This project is the result of a cooperative effort between the USDA and the private sector. The antigen was developed by scientists at the Genex Corp. in Rockville, MD, using antibodies produced by USDA scientists. This is the first antigen that confers protection against any species of coccidia by a method other than including actual infection. This breakthrough, when fully developed, will lead to a substantial saving for the individual poultry grower. And, I should add, that it would be just one example of new technologies being applied for the benefit of the small farmer as well as the larger scale operator.

I would now turn to the part of your request for information regarding the future directions for biotechnology research. It is in this area where many questions are raised regarding the impact of biotechnology research on farmers, on the environment, and on the consumer, and as you noted in your opening statement, Mr. Chairman.

We realize that new technologies mean changes for the farmer. And the recent study of the Office of Technology Assessment was, in my opinion, correct when it stated that farmers must take advantage of these new technologies if they are to remain competitive. However, this is not a new situation. The American farmers have generally adopted new methods and new systems enthusiastically. Our expectations are that through biotechnology, American farmers should be able to reduce the cost of inputs significantly and to make more efficient use of the land.

The future direction of biotechnology is being shaped now mainly through the cooperative efforts of USDA and the Division of Agriculture, Committee on Biotechnology of the National Association of State Universities and Land-Grant Colleges.

I am pleased to provide for the record a copy of the March 1985 progress report from the Committee on Biotechnology, which is entitled, "Emerging Biotechnologies in Agriculture: Issues and Policies." (See appendix A, p. 323.) We support the concept of a National Biological Impact Assessment Program and feel that the future of biotechnology is best served by having a coherent, rational, and unified system.

This document sets out a plan for an expanded national program to utilize existing scientists, research networks, and protocols to assess biological change in agriculture and related ecosystems. I agree that it is urgent to begin now to delineate appropriate and acceptable scientific methods for the assessment of the products developed using biotechnological processes.

To quote from the report:

> It is proposed that the National Biological Impact Assessment Program be established within the United States Department of Agriculture and its cooperating State institutions—State Agricultural Experiment Stations and the State Cooperative Extension Service—in order to capture the benefits of existing experience in the most economic and efficient manner. No other agency or organization could offer a comparable structure, geographic distribution of expertise, depth of experience, impartiality of assessment and proven scientific accomplishment. Duplication of this work would be costly and unjustified.

The mission of NBIAP, or the biological assessment program, would be to assess fairly, accurately, and continuously the impact of genetically altered organisms produced by genetic engineering research. This close and continued scrutiny by a national network of agricultural and allied scientists would enable the United States to gain maximum benefit from biotechnological research while assuring the greatest possible protection of society and the environment.

This last paragraph, incidentally, is an extension of the quotation from the March 1985 publication.

Mr. Chairman, I would ask that you and the members of the subcommittee take a few minutes to review this report. I believe you will be impressed with the planning effort which has been put forth. In my view, the future of biotechnology is tied closely to the development of such a coordinated effort.

I would be remiss if I did not comment briefly on the regulatory aspects of this issue. With biotechnology comes a tremendous responsibility. Scientists recognize this responsibility and will embrace those standards which are designed to protect the environment and the health of people. USDA, the EPA, the Department of Health and Human Services, the Office of Science and Technology Policy, and other Federal agencies are working closely together to assure that there are adequate safeguards in biotechnology research. I know you are going to address this subject in depth in tomorrow's hearing, but I do want you to know that the agricultural scientists know and share your concern for the development of responsible regulations.

This concludes my prepared remarks. As I said at the beginning, I have colleagues here who might wish to add to the presentation or are prepared to answer any questions you or members of your committee might have relative to this statement or other areas that you feel are germane to the issue. Thank you.

[The prepared statement of Dr. Bentley follows:]

TESTIMONY OF DR. ORVILLE G. BENTLEY

Good Afternoon:

I am pleased to have the opportunity to participate in these hearings on biotechnology and agriculture.

These are exciting times in the agricultural sciences, with new technologies holding great promise for finding solutions to some of the more difficult problems which have plagued the American farmer for many years and for providing innovative ways to reduce the costs of farming in the future. And, I hasten to add that these new technologies will provide the research scientists working in agriculture the tools to make further contributions to this Nation's important biomedical research program.

Mr. Chairman, you have asked me here today to describe the USDA's biotechnology research program, to provide insights into current advances in biotechnology research, and to discuss the direction future research may take.

Biotechnology, which can broadly be defined as the use of living organisms or their components in agriculture, food, and other industrial processes, is not something new to USDA and the agricultural research community. Agriculture has had a long history of improving our food, feed, and fiber through the introduction and improvement of new plants, animals, and micro-organisms. Indeed, virtually all our crop plants and animals in use today were developed in this manner.

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I would turn now to that part of your request for information regarding the future direction of biotechnology research. It is in this area where many questions are raised regarding the impact of biotechnology research on farmers, on the environment and on the consumer.

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This document sets out a plan for an expanded national program to utilize existing scientists, research networks and protocols to assess biological changes in agriculture and related ecosystems. I agree that it is urgent to begin now to delineate appropriate and acceptable scientific methods for the assessment of the products developed using biotechnological processes.

To quote from the March report: "It is proposed that the National Biological Impact Assessment Program (NBIAP) be established within the United States Department of Agriculture and its cooperating state institutions (State Agricultural Experiment Stations and the State Cooperative Extension Service) in order to capture the benefits of existing experience in the most economic and efficient manner. No other agency or organization could offer a comparable structure, geographic distribution of expertise, depth of experience, impartiality of assessment and proven scientific accomplishment. Duplication of this work would be costly and unjustified.

The mission of NBIAP would be to assess fairly, accurately and continuously the impacts of genetically altered organisms produced by genetic engineering research. This close and continuous scrutiny by a national network of agricultural and allied scientists would enable the United States of America to gain maximum benefit from biotechnological research while assuring the greatest possible protection of society and the environment."

Mr. Chairman, I would ask that you and the members of this Subcommittee take just a few minutes to review this report. I believe you will be impressed with the planning effort which has been put forth. In my view, the future of biotechnology is tied closely to the development of such a coordinated effort.

Mr. Chairman. I would be remiss if I did not comment on the regulatory aspects of this issue. With biotechnology comes a tremendous responsibility. Scientists recognize this responsibility and will embrace those standards which are designed to protect the environment and the health of people. USDA, the Environmental Protection Agency, the Department of Health and Human Services, the Office of Science and Technology Policy, and other Federal agencies are working closely together to assure that there are adequate safeguards in biotechnology research. I know you are going to address this subject in depth at tomorrow's hearing, but I do want you to know that the agricultural scientists know and share your concern for the development of responsible regulations.

That concludes my prepared remarks. I have with me today the administrator of the Agricultural Research Service, Dr. Terry B. Kinney, and the administrator of the Cooperative State Research Service, Dr. John Patrick Jordan. We will be pleased to respond to any questions you may have.

Mr. **Brown**. Thank you very much, Dr. Bentley. We would be pleased to have any remarks that Dr. Kinney or Dr. Jordan or Dr. Still might have.

Mr. **Bentley**. I think we would prefer to respond to questions, if you might have them, or amplifications in areas that you might think would be appropriate.

Mr. **Brown**. All right.

First, I would like to recognize Mr. Volkmer.

Mr. **Volkmer**. Let me try and do a few of them anyway.

There has been some concern, Dr. Bentley, that in the field as it is being developed so rapidly in biotechnology, especially in the agriculture area, do we believe that we will have an adequate supply of trained scientists in biotech?

Mr. **Bentley**. The anticipation is that, if the field expands and continues to expand as it does now, or has been, there will be problems in finding, or recruiting scientists both in the industry and in universities for some of the high priority areas or the ones that are developing the most rapidly.

I would add, though, that in the various reports—and I can't come up with the exact answers—but right now, as I recall, and I would like to have the opportunity to correct the record to the exact number, but I think there was something in the order of 800 to 1,000 graduate students in the United States today that are working on various biotechnology related projects.

I am saying that those are research programs that are under way at, in universities, and some of them cooperative. Within the USDA there are some postdoctorate fellows. There have been a number of those. I think the number—and again, I would want to defer for a correct number—275 people, I believe. Dr. Kinney nods his head that that is the correct number of various postdoctorates. Not all of them are necessarily involved in biotechnology. So, there is an extensive training program.

Moreover, I think that there is something happening that will help remedy or meet this question, that scientists from non—it would be nontraditional agricultural disciplines, that is, the basic sciences, are completing their work and finding career opportunities in the agriculturally related fields where biotechnology is being applied.

I know that this is true—I attended, listened to seminars and presentations made at several universities. I was, for my part, pleased to note that these scientists had come from universities where they had obtained basic background but not necessarily in agriculture. And they were learning to be a part of the agricultural research team.

Mr. **Volkmer**. Then you don't—well, let's put it this, put the question around a little bit. From what you're telling me, the research that is going on in the university level, much of it funded by the USDA, is developing graduate students——

Mr. **Bentley**. Yes.

Mr. **Volkmer** [continuing]. In the biotech area?

Mr. **Bentley**. I must be sure I add, though, that I think there will be a need for more people in these areas, and that that will be, if development continues as we anticipate it, I think that there will be a need for more people. And this is one of the reasons that we are challenging our universities to recruit more students to studies in the agricultural area, at the graduate as well as the undergraduate level. And I think that is part of the thing. I sort of took that as a given, but I must make that point explicitly, because there is need for more students and more people. But there is much going on now at the current time in an attempt to meet some of the immediate needs.

Mr. VOLKMER. I haven't had time to examine it, but the budget for 1986, appropriate level as what we had for 1985, in the cooperative research grant area.

Mr. BENTLEY. It——

Mr. VOLKMER. In other words, will we be able to continue approximately the same——

Mr. BENTLEY. Well, the recommendation——

Mr. VOLKMER [continuing]. Number——

Mr. BENTLEY [continuing]. By the budget recommendation is for a continuation of these programs in 1986 at the 1985 level.

Mr. VOLKMER. I want to thank you for bringing this to our attention on the progress report last year, and we will examine it. Thank you very much.

Thank you, Mr. Chairman.

Mr. BROWN. Thank you, Mr. Volkmer.

Mr. Packard?

Mr. PACKARD. Thank you, Mr. Chairman.

One of the concerns that we hear occasionally is the effect that biotechnology and agriculture will have on world production, whether it will create surpluses, whether it will relieve hunger, whether it will assist in balancing out trade and supply all food and fiber for the world. What is your opinion in respect to the effect that biotechnology and agriculture will have upon supply, production?

Mr. BENTLEY. I divide it into two parts. One is that, as new technologies are developed, they have the potential of one, increasing production per unit. That is, the bovine growth hormone in cattle. We have, if you come up with, can combine some genetic material as in plants, there's also reports of increased productivity in rice, yields per bushel. And one could go up and down the line. There are some of these kinds. There are those kinds of developments.

The second part of it is that biotechnology holds promise, as I see, Mr. Congressman, to reducing losses. As one can build greater pest resistance or tolerance, whether it's insects or diseases, or soil-borne diseases, or whatever it is, that will tend to increase yields or increase supply of product. It will at the same time perhaps increase quality, increase shelf life, and so on, which will also be important.

So, I would think that most people would agree that there is a potential for increasing the total production.

However, the second part of my answer is that the great excitement in biotechnology is in improving or reducing losses and making and reducing costs that are associated with control of disease and insects, et cetera, perhaps development of some technologies which can be used in combination with chemicals and management processes to deal with problems that have bothered farmers for centuries. The same ones around: weeds, insects, and so on.

And I would hope that in the process we can reduce input costs to make, to keep, or to help maintain a strong competitive position for the American farmer in production, in markets, and so on. I think that's a very important part of it.

Worldwide, many people feel that this might help, that biotechnology can increase production in the developing countries. And I would suspect it has that potential for it.

Mr. **Packard**. I think there's little question that the American farmer is struggling now with competition worldwide, with market prices, with surpluses, et cetera.

As a related issue, is our biotechnical research keeping pace or ahead of most of the rest of that of the world? Are we leading the way in this area?

Mr. **Bentley**. I should be sure in conditioning in responding to that question by saying that I will give my impression. I think there will be panelists before the committee that will have a better assessment of the world situation, those from industry and other places. But now let me give you my impression. My impression, we are a leader in the biotechnology areas. And we have the basic research programs that go back to the fifties and sixties, much of it funded through the NIH programs in medicine, biomedical field. We have got that basic research background and the capacity to develop. So, I think we are in a very strong position.

I have heard some people from the biotechnology industries point out that some of the countries that are in and potential competitors or are competitors do not have the research base that we have in this country. And therefore, that leads me to the conclusion that it is very important to us to maintain this position that we should be supporting research both in the basic or moving it from the basic to the applications stage, which requires studies, and so on.

Mr. **Packard**. In that connection, Dr. Bentley, is the better part of our research being done through the Department of Agriculture and other governmentally sponsored research programs, or is it being done with private research efforts?

Mr. **Bentley**. Again, I give my reaction. My reaction to that is the basic research programs are being—a lot of it is carried out within our universities, whether it be—I am including now in university research activities that are outside of the colleges of agriculture, but they do include the colleges of agriculture, veterinary medicine, forestry, where it's appropriate. And in industry, whereas in industry there is a certain amount of basic research, but much of the research by necessity in the industry is related to development of potentially new technologies and finding answers to questions that are related thereto.

I would not add, however, that there is not basic research. There is research being conducted in industry by several, in several major laboratories. But, a substantial amount of research is being done in this field, as it has traditionally in the USDA laboratories or the United States and in our universities.

Mr. **Packard**. So, you feel that it would not be a better use of our Federal dollars to make research grants to universities and private groups in preference to using those funds without our own governmental research programs?

Mr. **Bentley**. If I missed—do you mean I don't think we shouldn't have? Was the question, did I think we should or should not have grants?

Mr. **Packard**. I guess the question is, should we direct more of our funds or remain essentially where we are, or less of our funds toward private research grants, in preference to our own federally funded research projects?

Mr. **Bentley**. Well, I guess I define it by saying that there has to be a core program in the laboratories, whether it is in the Federal or the State agricultural experiment station, universities. We need to maintain that. But there is a great deal of merit to having some, having grant programs such as the one that we are initiating in fiscal 1985 that makes grants, competitive grants on the basis of the merits of the projects to universities, whether it be public or private universities, or whether it be in colleges of agriculture, to scientists in Federal agencies.

And I am not sure whether I can answer on the private laboratories or not. I don't know. I would have to check that point. But this is the basis of where we are making grants. And I see a great deal of merit in that, in targeting funds to a specific high priority area such as biotechnology. I think there is a great deal of merit to that.

I just want to add one caveat. I also think that we are in a new era in terms of relationships with the Federal agencies, Federal research establishment, and from our university research establishments with the private sector. There are all kinds of joint ventures that I am sure you are well aware of and heard of. They create in themselves some questions. They are different. They raise anxiety sometimes because they don't follow exactly the same patterns we have in the past.

But I think the nature of the science and the nature of the technological innovation calls for every bit of innovation and every bit of cooperative venture that we can undertake. Because we are really dealing, in my view, with a competitive position of science and technology in the country and then what it will mean to the industries that it will serve. In our case we are talking agriculture, the food and fiber industries, or if we are talking in the biomedical, pharmaceutical, the biologicals, in fermentation, chemistry, the fermentation processes, and all of these. I think when we deal in that kind of an issue, it seems to me we should try to mobilize all our resources, regardless of where they are, and try to be sure that we put our efforts to bear on high priority needs.

Mr. **Packard**. Thank you.

Mr. **Brown**. Mr. Reid?

Mr. **Reid**. I have no questions.

Mr. **Brown**. Mr. Morrison?

Mr. **Morrison**. Thank you, Mr. Chairman.

Is it an accurate assumption that this is one of the agricultural issues that does not interfere with the ongoing arguments about big farms versus small farms? For instance, the things you develop through biotechnology will in fact be as applicable in one area as in another, because we're not talking about capital costs. Is that accurate?

Mr. **Bentley**. I think that's an accurate statement, yes. That is, you can apply increase—you know, in seed technology, one can buy the seed and utilize that technology through that route, whether it's generated through biotechnology or through the traditional patterns, which is a form of biotechnology. I think you're right.

Mr. MORRISON. So, those of us who believe that family farms can be just as competitive as corporate conglomerates shouldn't be bothered by this issue, in fact, we should be very supportive?

Mr. BROWN. You're still dreaming, regardless of what happens on it.

Mr. MORRISON. OK, right.

Mr. BENTLEY. I would answer yes.

Mr. MORRISON. I am sort of interested, as I look at your funding, on the difference between your programs that are handled by Agricultural Research Service as opposed to the Cooperative State Research Service. Could you clarify that balance for me? Who does what and why?

Mr. BENTLEY. May I call on my colleagues to answer here? Do you want to start? Which one do you want? Do you want to start first? All right.

Mr. KINNEY. Mr. Morrison, the basic difference between what ARS does and what the universities do is rather subtle. But basically the Agricultural Research Service, because our appropriations are made directly from Congress, is responsible for problem solving in every case. So, we don't, unless it's directly related to a problem, we don't indulge in basic research as we sometimes know it in public or private universities.

There is probably one exception to that, and Dr. Still is here today. He is the director of our Plant Gene Expression Center in California, or acting director. We formed that Plant Gene Expression Center to do some research that we feel no other research group will undertake. That is, some long-term, high-risk research relating to defining gene expression and discovering how genes express themselves within a cell or when moved from one plant to another, and how we control that expression. That is a fundamental problem. We think ARS can play an important role.

Other than that, our research is directly related to solving problems as funds are appropriated by the Congress for those, to address those problems.

I think Dr. Jordan may want to add additionally. Perhaps first Dr. Still might want to comment additionally.

Mr. STILL. A general comment: when you look where the field of science is going—and Mr. Packard's question—I think we have to realize that this technology was invented, for the most part, in the United States. And that we want to look at that opportunity and what brought that to fruition was capital investment by this Nation post-Sputnik in the human resource, young people, minds, in the university system and in centrally managed institutions like the Agricultural Research Service.

There are those who have concern that, like the computer industry and the chip industry, that we will export this technology before our farmers and ranchers can capitalize on it. So, to paraphrase what Mr. Morrison was asking, as a farmer on this panel, I think we have to look at long-term opportunities for our farmers and ranchers. We have to look at opportunities to avoid the short-term crisis of red ink. But I would paraphrase that the future is efficiencies and giving farmers and ranchers opportunities through technology to increase their efficiencies.

Now, whether that is expressed in terms of bushels per acre in commerce, that's how the market runs. So——

Mr. PACKARD. Take it one cow per congressional district, would just about do it.

Mr. STILL. Well, Dr. Marvel is in the audience here, and he can help us on growth hormone. That may be real efficiencies, but I haven't found a free lunch in agriculture yet. There may be one.

But I think, if you look at water, for example, and land, the frontier is now. We can't put any more water on the Yakima Valley, I don't think. I think we've got her out there. So, now what we need to do is to develop technology, the agricultural aggregate to better utilize that water and better utilize that land and better utilize that resource. And I think we are going to do that through management, of which biotechnology is a part. I don't believe it's a panacea. I think it is a part.

The corporate groups who we are representing here, in my assessment, are probably the best in the world to deliver that technology. But what they need is the fundamental knowledge to evolve that technology. A simply analogy would be the one that we have talked about in these chambers in the last few years, and that is the hoof-and-mouth disease. Fundamental knowledge of that virus is in part a result of investment of the people of this Nation in Plum Island and ARS and in the university system.

Now, the fact that that knowledge base has been able to be extrapolated through biotechnology into what will be a vaccine is a result of a lot of treasure from the public sector directed at a real-world agricultural problem, which you gentlemen recognize is much broader than the boundaries of our country.

So, what Dr. Kinney is proposing in institutions like the Plant Gene Expression Center, it will work with our universities and our industrial partners, is to lay a foundation of knowledge of science for agriculture and plants so that we can understand how plant genes are organized, how those organized structures are related. And most important is how we can affect, manage, if you will, the expression of those genes in a way that will increase the real efficiencies of land, water, and resource and tailor those agricultural products to commerce.

Now, that's a big chunk of agricultural research. We are talking about research for agriculture.

Mr. PACKARD. Thank you. I appreciate that very much. I would like to hear from Mr. Jordan, if that's all right.

Mr. JORDAN. The big difference is that the Cooperative State Research Service provides partial support for the university system and its research component, particularly the State Agricultural Experiment Station System. And it therefore is a kind of a bottoms-up program planned at the local level to meet the needs of the States and territories and is amassed at a national level through CSRS Program staff together with the State directors.

What we really end up doing, Congressman Morrison, as you well know, it leverages into a system about $4 for every dollar of the Federal money put in there. CSRS provides about 19 percent of the funding for the State agricultural experiment stations on the average.

In terms of biotechnology, there is a great deal of that basic work that is inherent in teaching graduate students and deriving this newer knowledge. In the system for agriculture alone, there is $46 million in the current year's budget, in CSRS, for biotechnology, including the new expanded biotechnology competitive grants program, which is just being unleashed this year. Add to that another $30 million that the system has brought in from other resources, including State funding and competitive grants from the National Science Foundation, the National Institutes of Health, and so forth, and you get an idea of the size and scope of the dimension.

So, a good $75 million worth of activity is going on out there. And that is a very significant contribution to the development, Congressman Volkmer, to the issue of new students that are on the cutting edge of biotechnology for tomorrow. Really what we are doing here is, although we are dealing with some of the same principles that we have over many years, the rate at which we can move toward those goals has been changed markedly since we are able to address the issues at the tissue, at the cellular, and at the molecular level.

Mr. MORRISON. Thank you.

Chairman Volkmer, if it's all right with you, I think it is appropriate that the record show that Chairman Brown in his former incarnation as the chairman of the Department of Oversight and Review at the Department of Agriculture, is probably responsible for much of the growth that we see now reflected in what I sense is a very enthusiastic attitude by the panel here in front of us. Mr. Chairman, I would like to pay tribute in respect for those efforts through the years.

Mr. BROWN. I appreciate that very much, and I will take all the credit I can get for influencing this administration, because I don't get a chance to influence it very much.

Let me explore a little bit this Plant Gene Expression Center. It seems to me a little bit unique that this is funded through the ARS. I am correct in that, am I not?

It would seem, just off the top of my head, that it might be more compatible in the Cooperative State Research Service budget.

Mr. KINNEY. I think, Mr. Chairman, you—we need to first of all establish the fact that the concept for this Plant Gene Expression Center was originated in part with, primarily in the Agricultural Research Service with the thinking of people like Dr. Still and others.

We recognized an opportunity there, a unique opportunity there in California because of the proximity of the Western Regional Research Center and the University of California there at Berkeley for a cooperative effort. We discussed this with university people. They were equally enthused. So, it has evolved over time.

I think, with all due respect, there is a great advantage to having this done, because the Plant Gene Expression Center is coming on line now, about a little more than 1½ years after it was conceived. And that is not possible, Mr. Chairman, and you know that, with having major facilities and a major cooperative effort and hiring of scientists, and so forth, take place, I think, in a short time, because it is part of our evolving program.

Dr. Still may want to comment further. He has been out there for several months now developing this center.

Mr. STILL. Chairman Brown, the problem that Dr. Kinney was looking at in trying to make a decision on where to implement such an activity was that there are obviously a number of locations in our country that certainly would have been ideal. But when you really take a good hard look at particularly—and remember, this is plant molecular biology we are talking about. There is a tremendous concentration of expertise in the bay area.

If you take the circle and include Dublin with ARCO Research and go north to Davis, CA, and swing to the south bay and pick up Stanford, not to mention the University of California at San Francisco, where this technology was spawned, and recognize that we have a full partner, and we should be aware that the Plant Gene Expression Center has not only the Agricultural Research Service on the marquee, but we are in full partnership with the University of California at Berkeley and the California Agricultural Experiment Stations.

The reason for that is that we have a management team that will consist of two lead scientists that are in fact University of California Berkeley professors, and the director. We also in this partnership have the unique opportunity for the land mass 14 field sites under the control of the State experiment station.

So, we have the unique opportunity to have environments running from the Mexican border to the California border and from sea level to the dry highlands of the eastern part of the State. So, we look at this as a unique opportunity to perform research.

The other thing that is unique about the center is it is divided in two parts. There will be a core of about 30 Ph.D's that will be stationed in the Albany-Berkeley area. But the consortium will consist of scientists scattered in both public and private institutions across our country and perhaps foreign operators. And the reason for this is we really believe that, if we are going to have an impact on hard red winter wheat, that we need first full partners who have that expertise and that germ plasm and, most important, that environment. So, the consortium then of the center will reach out with Nebraska, Kansas, et cetera, where that expertise is, because what we want to do in the Plant Gene Expression Center is to begin to evolve technology that is applicable in the hands of farmers and ranchers and seedsmen. We feel that by using the consortium we can bring in that expertise that exists in the State system, that expertise that exists in the private sector, to shorten the time lines. And we feel that is critical.

So, that is why, Chairman Brown, we are where we are. We must remember that the Agricultural Research Service is mission oriented, that we exist to solve problems for agriculture. And we firmly believe that the center can bring together a critical mass and focus that critical mass of heterogeneous expertise on the problem of plant genes and begin to build an environment where partners from industry and partners from the university can in fact begin to evolve technology that can impact on cotton, impact on small grains, impact upon the fruit industry.

We feel that this Nation needs that. I do not want to see the opportunity of biotechnology exported. I would like to see it exported in products that say made in the United States by U.S. farmers.

Mr. BROWN. Well, I appreciate that eloquent defense and description of the center. I didn't intend to be critical. I am just trying to get organized in the rationale for both the organizational structure and the funding structure here so that I can make a reasonable defense of it.

Mr. KINNEY. I didn't really answer your question, Congressman Brown. The answer to your question is that it would be unlikely that this sort of an arrangement, a cooperative endeavor involving the universities, industry, and ARS could be accomplished in the same way through either Hatch funding or competitive grant funding, because the effort, as we see it, requires a long-term commitment.

We also have to remember that this effort was really started by redirecting several million dollars in ARS funding from other areas into this area.

Mr. BROWN. Are you able to use competitive grant funding for the research work being done at the center?

Mr. KINNEY. Oh, you bet we will.

Mr. BROWN. Dr. Bentley, perhaps I should ask you this. In the overall funding for biotechnology obviously you are directing certain ARS funds into the field. I presume that there are at the various land-grant institutions programs in this field which would be funded in part through the cooperative State program. And then you have the competitive grant program.

Can you kind of help me to identify the relative priorities or amounts that come from each of these different streams to make up the total that is going into this field now?

Mr. BENTLEY. I think I can start on this. In the first place——

Mr. BROWN. I don't want to be picky about it.

Mr. BENTLEY. No, I know.

I think we say in the statement about $75 million is being spent from the USDA and the State universities. Of that amount, in addition to that—that's USDA Federal money—in addition to that, there's $30 million that is coming from non-Federal sources. A lot of that, most of that is in the experiment stations. Some of it is private grants and some with State funding.

Of the $75 million, $20 million is in the competitive grants program. So, it would be about a third.

Now, when you answer questions like that, you always have to put the caveat there are some other funds in the competitive grants area that is going to spill over and be related to biotechnology. But that is about the size of the program as we have it determined as of now.

I want to turn to Dr. Jordan to be sure, and Dr. Kinney, in terms of how I interpret my own statement here, if I reported it correctly. I think I have.

Mr. BROWN. All right. I have a sheet that has just been handed to me, giving the funding history for biotechnology research. (See appendix B, p. 351.) This shows a slight decrease for the fiscal year 1986 budget, Dr. Bentley. Adding up all of the different components and so forth, it shows 75 million, roughly, in 1985 and then 70 million, roughly, in 1986. Is this a matter of concern to you? You indicated that you were projecting a continuation of the 1985 levels, and this is relatively close, but it is still not—if you look at also the factor of inflation, you are going to take a little bit of a reduction here.

Mr. **Bentley**. The explanation as to the difference here, I can't right at the moment identify it other than they are on some special grants that were not included as a part of the budget recommendation for 1986. Because we are going to maintain the competitive grants program, I think the figure was at 46, yes?

Mr. **Brown**. Same level——

Mr. **Bentley**. Yes, same level. And that the ARS budget would be roughly at the same level, although there are some adjustments made there.

Mr. **Brown**. I don't quite see where the reductions are myself offhand, except it looks like the Forest Service has had some reductions.

Mr **Jordan**. There are two places, Congressman Brown. One of them is in the special grants area. That is, there is a certain amount of that $27.3 million that really has biotechnology relevance to it. The other part is that at this stage there has not been a recommendation to continue the Forest Service competitive grants program, which has a significant amount of biotechnology with it.

Mr. **Bentley**. That fund, on the request of the Forest Service, is being administered and processed and handled through the competitive grants program and agriculture. So, this would be the difference.

Now, I would anticipate in 1986 some increases because some universities are expanding their programs in this area. More joint university-industry arrangements you read about frequently. Some of those are rather substantial programs and extend over some period of time.

Mr. **Brown**. To achieve the kind of goals that Mr. Volkmer was referring to with regard to the bringing in of new personnel into this field, if we are going to follow a model anywhere like what happened in human health and biology, the funding programs for research conducted by the NIH—and it's quite correct to say we have made the progress we have because we have invested in trained minds—you are going to have to have a program that has an assurance of stability and growth or you won't get bright young people to come into it. You well recognize that, and I am sure the administration recognizes it.

Mr. **Bentley**. Yes.

I might add that in an earlier issue of the report of the National Association of Land-Grant College, Division of Agriculture Committee, they recommended a substantial program, a scholarship program, and so forth, for achieving just that particular purpose. That part of the program recommendation has never been funded, has not been funded. But we do know that inherent in the competitive grants that are awarded to especially universities, that there will be a considerable amount of that money expended to support students at the graduate or postgraduate level. And that will attract some into the field.

But whether that will be enough or not is something that it is hard for one to answer. I guess I go back to saying, though, that as a national policy it seems to me that an appropriate role, a very important role of government, whether at the State, the university system, or the Federal Establishment, is the training of people to be qualified to meet the needs of the future.

When you think about change and think about coming up with new and innovative ideas, it, of course, has in—its genesis has to be the intellectual capacity to do it, coupled with the energy and the desire to do it, the incentive to do it. And that is something I think we have to keep track of. And as a former dean of a college of agriculture, I would say we have not given enough attention to that; otherwise, I wouldn't be true to my 25 years of arguing for that topic.

Mr. **Brown**. Mr. Jordan, did you wish to make a comment?

Mr. **Jordan**. I would like to point out, Mr. Chairman, that in the proposed 1985 farm bill is a very important component that speaks to part of this issue, namely a revision of the facilities act which would provide not only for facilities but also equipment that could be used for research, extension, and teaching, all of which are going to be needed to deliver this. Because, after all, the science that is developed and not delivered to the farmer/rancher is not going to have the impact that we are hunting for.

So, that particular component is one of the big wish areas for the administration in that farm bill, sir.

Mr. **Brown**. We appreciate your reminding us of that.

Mr. Morrison?

Mr. **Morrison**. I think it's in line with the subject area we are discussing. Just a very basic question: how transferable is this technology between the plant and animal kingdoms? In other words, some of the molecular dealings that you have, are they—can you learn from work being done by others?

Mr. **Still**. Mr. Morrison, we have to realize that the biotechnology that we are drawing on has come out of, in great part, funding for medical research. In all due respect to this body, had some of you succumbed to a plant disease, there would probably have been more enthusiasm for funding basic plant research.

Having said that, the basic technologies that we are applying originally came from cell biology, biochemistry, and genetics. So, what we're doing now are drawing individuals from that resource pool and bringing it into the universities and making the transfer to plants and other microbial systems.

Let me also make one point. When you are talking about biotechnology for agriculture, that agriculture is a very heterogeneous environment. It is not one simple system like homo sapiens, man. So, we need a great deal of emphasis in this area. But we are started. I think that you gentlemen have recognized this need, and the increased funding that has been made available to the agricultural community, through industry and through the public sector is being reflected. And as you go out—and my colleagues from industry who will be testifying here soon and those of us in ARS and in universities look for personnel. We are seeing a greater pool. But we must recognize that a great many of these people who have wanted to do particularly plant research in the past have had to take their training in institutions linked to the National Institutes of Health because that is where the funding was.

So, we are seeing encouraging beginning, but I must testify we have only begun.

Mr. MORRISON. Thank you, Mr. Chairman. I thought that related to both fields.

Mr. BROWN. Sometime when we get the opportunity—I don't want to pursue it now—I would like to get on the record more about your long-range or or 5-year plans for funding growth and how it relates to the development in this area. But because we have a couple of other panels this afternoon, I think we will defer that for the time being.

I want to thank all of you gentlemen for setting the stage for us in this area. I assure you that we will continue our strong interest in the promotion of the research that you are engaged in here.

Thank you very much.

Mr. BENTLEY. Thank you.

Mr. BROWN. There may be some questions that we would like to address to you in writing for the record. We trust we will have your cooperation in responding.

Mr. BENTLEY. Thank you. We would be delighted to respond to these questions. We would also be delighted to discuss the matter of priorities because we continue to have a high priority for this area in all of our planning activity, the joint counsel and other bodies that have looked at research needs for the future and linking to extension education and training.

(See appendix C, p. 352.)

Mr. BROWN. Thank you very much.

Our next panel will be representative of the industry efforts in this field. I would like to invite Dr. John Marvel from Monsanto Co.; Dr. Jerry Caulder, from Mycogen Corp.; and Dr. J. Eugene Fox, from ARCO Research to come to the table.

Gentlemen, I know that you are all deeply involved in this field and probably have a sense for its potential importance and impact upon our agricultural economy that is superior to any other similar group of people. We appreciate your being here this afternoon.

Do you want to lead off, Dr. Marvel, and tell us what great things Monsanto is doing?

Dr. MARVEL. I will make an effort to do that.

STATEMENTS OF JOHN MARVEL, MONSANTO CO.; JERRY CAULDER, PRESIDENT, MYCOGEN CORP.; AND J. EUGENE FOX, ARCO RESEARCH

Dr. MARVEL. I would like to express my sympathy to Mr. Volkmer and his problems with laryngitis and express my appreciation for being able to address the subcommittee.

I think that the things I would like to talk about is to touch briefly on the importance of agriculture, which this committee probably doesn't need too much background on. I would like to talk about some of what I think are the primary thrusts in biotechnology which include at least three specific kinds of examples of things that are going on right now at Monsanto. And, finally, address several concerns which I think are shared by the agricultural community as a whole, some of which you have touched on probably in this last panel.

I think, if you look at the benefits of agriculture, they are well documented, and they were also attested to, I think, in the last AG day in one of the President's addresses. But I think the real place where you really see that benefit is in the supermarket when you go to buy your food. If you have ever bought food in some other part of the world, you can see what agriculture has been able to do.

I think the other parameter on that, which in a sense talks to the question that Mr. Packard had raised earlier, is that every day there are about 210,000 more people to feed in the world. Calculated out, that means that in principle you should have to double the agricultural production in the next 40 years. And I don't know whether that is going to mean we are going to have surpluses or negative, or something else for a myriad of reasons, which I doubt if anybody can predict accurately right now.

But I think the past advances in plant and animal production have been significant, if not awesome. And I think that the potential gains to be achieved using that technology—we are still gaining with that technology—but they are being done at a decreasing rate.

I think you are in great need of new breakthroughs in order to push technology on the farm to meet the needs of the next century, particularly if U.S. agriculture is to remain cost competitive with the world.

Biotechnology is an area where we are just beginning to glimpse the immense potential for agriculture: in crops with better disease and pest resistance, higher protein content and greater tolerance of stress from drought, poor soils or temperature extremes, to name a few.

To achieve these goals, I think future agricultural research will increasingly focus on biotechnology as a tool that scientists can use to help meet some of the crucial needs of mankind. In a general sense, I think, as Orville said, "biotechnology is the use of living organisms, their components or derivatives to create new products in agriculture, pharmaceuticals, food, and other areas." Biotechnology is a process, a way of conducting research, not necessarily a product in and of itself.

Each year a large percentage of the world's crops are lost to insects, disease, and weeds. I think it is clear that there is room for considerable improvement in the techniques used to control those pests.

Microbial pesticides, as an example, could provide a range of new pesticide products that are essentially harmless to man and animals, ecologically sound, highly efficient, and selective to the target organisms. Plant genetic engineering could produce plants with genes to code for toxin production within the plant cells, thus producing plant resistance at both a reduced cost and with increased environmental safety over present control measures.

A second important application of biotechnology in crop production: some potential crop improvements, that can result from genetic engineering in plants, include more efficient fertilizer assimilation, increases in herbicide and insect resistance, enhanced seed oil protein production, increased photosynthetic capability, improved breadmaking qualities in grain, and the development of crops better suited to marginal environments, for just a few examples.

Other important applications of biotechnology in agriculture—or another important one will be in animal production. Several different approaches to increasing animal protein content are being explored using biotechnology. Some of the areas actively being researched include the production of growth hormones, amino acid production for feed supplements, and vaccine for hoof-and-mouth disease, scours, and other diseases.

Monsanto is active in all the areas of research we have thus far discussed. We have shown our strong belief in the future of biotechnology with the recent dedication of our new life sciences research facilities, which mark the largest single investment in research facilities in Monsanto's history, well over $150 million that we have committed to an increasing focus on the life sciences.

The application of biotechnology to pest control is an exciting area of research. Monsanto is applying genetic engineering technology to try to discover new ways to control pests that damage plant roots, as an example.

In nature some bacteria produce chemicals which control specific pests, while other bacteria live in the soil in close association with plant roots. Using genetic engineering techniques, Monsanto is investigating whether the gene controlling chemical production in one kind of bacterium can be transferred into the soil bacterium, providing it with the ability to protect the plant roots from soil-dwelling insect pests. If successful, this method will provide more efficient, more effective pest control.

Last December, we applied to the EPA, in accordance with its interim policy, for permission to field test a genetically engineered bacterium with the capability to produce an insecticide. Our notification and supporting research data comprise three volumes and more than 800 pages.

Our preparation for this small-scale field test, done almost 3 years earlier than we would normally do work of this sort for something that we were considering for commercialization, has been extremely thorough, and we have extensive data on both the bacterium we plan to test and on the insecticide it will produce, with the added gene from *Bacillus thuringiensis*, an organism that has been registered and used for more than 20 years.

In the plant science area, we are looking at imparting herbicide resistance into crops. This could allow the use of broad spectrum herbicides with reduced crop toxicity, which would enhance crop yield as well as quality.

We are also involved in other areas of plant biotechnology research. For example, our laboratories were the first to develop cell culture techniques for soybeans. Further, we have been able to transfer bacterial genes into plants and had those genes expressed in the plant.

We are also very active in animal production research. We believe we can make our most effective contribution by helping farmers achieve optimum efficiency in their operations. One way to do this is to help them get the maximum yield from their animals within the animal's natural genetic range. For example, the average dairy cow gives approximately 12,000 pounds of milk per year. But a champion cow has given over 50,000 pounds of milk. So, obviously, there is a great potential for productivity increases.

This is our objective with what we call MBS, methionyl bovine somatotropin, to move this concept for improved efficiency of milk production through research and development to its ultimate expression as a useful commercial product. MBS has increased milk production by 20 percent or more and improved the cow's utilization of feed in research trials. We believe this will lower the cost of production for the dairy farmer.

Obviously, we are still in a research stage with many of these potential biotechnology derived products. MBS must still go through regulatory clearance and may be available for commercialization by the end of this decade. Other products will be longer in coming, perhaps another 10 years or more.

We believe that agricultural policy must continue to encourage research in Government, academia and industry, and must anticipate how changing technology will affect agriculture.

All three sectors of the agricultural research system have a vital role to play. Government is an important factor in adapting U.S. agricultural research goals to meet changing needs. Support programs are carried out, not only in the USDA but also in the National Institutes of Health, the National Science Foundation, and the Department of Defense. State and private universities are receiving funding from these agencies for agriculture-related research and training.

Each sector makes their contribution, but there is a need, in our view, to coordinate and track these efforts. The Agricultural Research Service within USDA should be well suited to fill that coordination role. It could become the lead agency for conducting public agricultural research of national importance. Furthermore, it could help to set a national perspective on agricultural priorities and the research needed to support those priorities.

The greatest obstacle to the enormous potential of biotechnology research is not lack of interest or lack of effort, but it is our sheer lack of basic knowledge about plants. We need much more research in plant biochemistry, plant physiology, and molecular genetics, among other disciplines. We have fundamental work to do. The knowledge gap in these plant sciences is too large, and it prohibits the rapid exploitation of biotechnology in agriculture.

Government should continue and increase its support of research in the basic life sciences with emphasis on plants and animals, if the full fruit of biotechnology is to be realized. Increased funding in graduate fellowships, competitive grants, and instrumentation grants must be undertaken in the agricultural area, if America is to stay cost competitive in agriculture.

Industry's primary and proper role is to translate basic knowledge into effective products for agriculture. This is a role that Monsanto accepts. The company spends in excess of $100 million a year on agricultural research worldwide. This commitment, plus those from many other companies, will provide agriculture with new technological products.

Academia has a dual role: First, to train new scientists for agriculture; and second, to conduct basic and practical research. While this research and training are often funded by Government, a growing collaboration between universities and industry provides a buffer against swings in Government funding. This collaboration of public and private support, we believe, is strengthening the entire research system.

The final point I want to make today is our belief that biotechnology must be subjected to sound regulation for its successful application, and the environment must be protected. The potential risks from biotechnology are manageable, and regulations are needed for that management.

Second, and equally important, the public must perceive that they and the environment are being protected. They must have confidence that research is being conducted by responsible scientists with the approval of responsible regulators. In that way the public may be able to reap the benefits of new scientific breakthroughs without unnecessary delays or concerns.

Success in achieving major technological breakthroughs is neither guaranteed nor is it predictable. And I believe work must begin now if we are to find and develop the agroscience winners that we need for America's future.

Thank you.

Mr. BROWN. Thank you very much, Dr. Marvel. I commend you especially for that last statement with regard to regulation. That is an example of corporate statesmanship on your part.

Dr. MARVEL. Thank you.

[The prepared statement of Dr. Marvel follows:]

PREPARED STATEMENT OF DR. JOHN T. MARVEL

Dr. John T. Marvel April 16, 1985

Mr. Chairman and distinguished members of the Subcommittee: I am Dr. John T. Marvel, General Manager of Monsanto Agricultural Products Company's Research Division. Monsanto Agricultural Products Company is an operating unit of Monsanto Company with over one billion dollars in agricultural product sales in 1984.

I am also a member of the U.S.D.A. National Agricultural Research and Extension Users Advisory Board, the Industrial Research Institute Federal Science and Technology Subcommittee on Agriculture, the Congressional Office of Technology Assessment's Advisory Panel for Technology, Public Policy, and the Changing Structure of American Agriculture, and a participant on several other agriculture related committees. In addition, I am an active manager of a family farm in central Illinois.

I appreciate this opportunity to discuss with you our views on the future direction of biotechnology and agricultural research.

Today we will briefly review the importance of agriculture to the United States and to worldwide food needs. Then I will address what I believe will be some of the primary thrusts of future biotechnology and agricultural research. I shall include three illustrations of the future which are taking place right now at Monsanto. Finally, I want to address several concerns which I believe are shared by the agricultural community as a whole.

Agriculture is the largest industry in the world. The importance of agriculture in America - relative to employment, gross national product, and the balance of trade - has been well documented. We see its benefits everytime we go to the supermarket. Our food bills are among the lowest in the world. Agriculture represents the largest single contribution to our balance of payments.

Today nearly one-third of the world's population is hungry, and every day there are 210,000 more people to feed. Only eight countries in the world consistently produce more food than they consume. With the global population growing at approximately 1.8 percent per year, we will need to double our food production within the next 40 years, if we are to keep pace with that growth, most of which will occur in Third World countries.

Past advances in plant and animal production have been significant, but the potential gains to be achieved using the old technology are decreasing. New breakthroughs are needed to push technology on the farm to meet the needs of the 21st century, particularly if United States agriculture is to remain cost-competitive.

Biotechnology is a major area where we are just beginning to glimpse the immense potential for agriculture, in crops with better disease and pest resistance, higher protein content, and greater tolerance of stress from drought, poor soils or temperature extremes. To achieve these goals, future agricultural research will increasingly focus on biotechnology as a tool that scientists can use to help meet some of the crucial physical needs of mankind.

In a general sense, biotechnology is the use of living organisms, their components, or derivatives to create new products in agriculture, pharmaceuticals, and food. Biotechnology is a process, a way of conducting research, not necessarily a product in itself.

Each year a large percentage of the world's food crops is lost to insects, disease, and weeds. Clearly, more effective pest control techniques must be developed. Microbial pesticides could provide a range of new pesticide products that are harmless to man and animals, ecologically sound, highly efficient, and selective to the target organism. Plant genetic engineering could produce plants with genes to code for toxin production within the plant cells, thus producing pest resistance at both a reduced cost and with increased environmental safety over present control measures.

A second important application of biotechnology is in crop production. Some potential crop improvements that can result from genetic engineering include: more efficient fertilizer assimilation, increases in herbicide and insect resistance, enhanced seed oil protein production, increased photosynthetic capacity, improved bread-making qualities in grain, and the development of crops better suited to marginal environments, just to mention a few.

Another important application of biotechnology in agriculture will be in animal production. Several different approaches to increasing animal protein content are being explored using biotechnology. Some of the areas actively being researched include the production of growth hormones, amino acid production for feed supplements, and vaccines for hoof-and-mouth disease, scours and other diseases.

Monsanto is active in all the areas of research we have thus far discussed. We have shown our strong belief in the future of biotechnology with the recent dedication of our new life sciences research facilities. This marks the largest single investment in research facilities in Monsanto's history, well over $150 million dollars. Monsanto is committed to an increasing focus on the life sciences.

The application of biotechnology to pest control is an exciting area of research. Monsanto is applying genetic engineering technology to discover new ways to control pests that damage plant roots.

In nature some bacteria produce chemicals which control specific pests, while other bacteria live in the soil in close association with plant roots. Using genetic engineering techniques, Monsanto is investigating whether the gene controlling chemical production in one kind of bacterium can be transferred into the soil bacterium, providing it with the ability to protect the plant roots from soil-dwelling insect pests. If successful, this method will provide more efficient, more effective pest control.

Last December we applied to the EPA, in accordance with its interim policy, for permission to field test a genetically engineered bacterium with the capability to produce an insecticide. Our notification and the supporting research data comprised three volumes and more than 800 pages.

Our preparation for this small scale field test has been very thorough. We have extensive data on both the bacterium we plan to test, and on the insecticide it will produce with the added gene from Bacillus thuringiensis (this toxin producing organism has been registered and used for more than 20 years).

In the plant science area we are looking at imparting herbicide resistance into crop plants. This would allow the use of broad spectrum herbicides with reduced crop toxicity which would enhance crop yield and quality.

Currently we are experimenting with strains of alfalfa that are resistant to our herbicide Roundup". Alfalfa tissue was placed into culture, and the cells were exposed to a lethal dose of Roundup" herbicide. Cells which survived this exposure were plated out for regeneration into whole plants. These new plants (or variants) were transplanted into the field and treated with Roundup" as a farmer would use it. Several variants exhibited resistance to the herbicide in the field. At the same time, other agronomic characteristics of the plant - standability, morphology and disease resistance - appeared to be unchanged by the selection and regeneration process.

Our evaluation process is by no means complete, and several more years of field tests will be required before this experiment can be declared a complete success. Nevertheless, it illustrates the potential utility of this kind of technology for crop improvement.

We are also involved in other areas of plant biotechnology research. For example, our laboratories were the first to develop cell culture techniques for soybeans. Further, we have been able to transfer bacterial genes into plants and had those genes expressed in the plant.

We are also very active in animal production research. We believe we can make our most effective contribution by helping farmers achieve optimum efficiency in their operations. One way to do this is to help them get the maximum yield from their animals within the animal's natural genetic range.

The average dairy cow gives approximately 12,000 pounds of milk per year; but a champion cow, in one year, has given over 50,000 pounds of milk. So obviously there is great potential for productivity increases.

This is our objective with MBS - methionyl bovine somatotropin - to move this concept for improved efficiency of milk production through research and development to its ultimate expression as a useful commercial product. MBS has increased milk production by 20% or more and improved the cow's utilization of feed in research trials. This will lower the cost of production for the dairy farmer.

Obviously we are still in the research stage with many of these potential biotechnology derived products. MBS must still go through regulatory clearance and may be available for commercialization by the end of this decade. Other products will be longer in coming, in perhaps another ten years or more.

Research is the key to more efficient and profitable production in agriculture. The effective use of new technology is an important reason for America's agricultural strength. We believe that agricultural policy must continue to encourage research in government, academia and industry, and it must anticipate how changing technology will affect agriculture.

All three sectors of the agricultural research system have a vital role to play. Government is an important factor in adapting United States agricultural research goals to meet changing needs. Support programs are carried out, not only in the U.S. Department of Agriculture, but also in the National Institute of Health, the National Science Foundation, and the Department of Defense. State and private universities receive funding from these agencies for agriculture-related research and training.

Each sector makes their contribution, but there is a need to coordinate and track these efforts. The Agricultural Research Service within USDA is well suited to fill that coordination role. It could become the lead agency for conducting public agricultural research of national importance.

Furthermore, it could help set a national perspective on agricultural priorities and the research needed to support those priorities.

The greatest obstacle to the enormous potential of biotechnology research is not lack of interest or lack of effort, but it is our sheer lack of basic knowledge about plants. We need more research in plant biochemistry, plant physiology, and molecular genetics, among other disciplines. We have fundamental work to do. The knowledge gap in these plant sciences is too large, and it prohibits the rapid exploitation of biotechnology in agriculture.

The government should continue and increase its support of research in the basic life sciences with emphasis on plants and animals, if the full fruit of biotechnology is to be realized. Increased funding in graduate fellowships, competitive grants, and instrumentation grants must be undertaken in the agricultural area.

Industry's primary and proper role is to translate basic knowledge into effective products for agriculture. This is a role that Monsanto accepts. The company spends in excess of $100 million dollars per year on agricultural research worldwide. This commitment, plus those from many other companies, will provide agriculture with new technological products.

Academia has a dual role: First, to train new scientists for agriculture; and second, to conduct basic and practical research. While this research and training are often funded by government, a growing collaboration between universities and industry provides a buffer against swings in government funding. This collaboration of public and private support is strengthening the entire research system.

The final point I want to make today is our belief that biotechnology must be subjected to sound regulation for its successful application, and the environment must be protected. The potential risks from biotechnology are manageable, and regulations are needed for that management.

Second, and equally important, the public must perceive that they and the environment are being protected. They must have confidence that research is being conducted by responsible scientists with the approval of responsible regulators. In that way the public will be able to reap the benefits of new scientific breakthroughs without unnecessary delays or concerns.

Success in achieving major technological breakthroughs is neither guaranteed nor predictable. Work must begin now if we are to find and develop the agroscience winners we need for the future.

Thank you.

Mr. **Brown**. Dr. Caulder, would you like to proceed next?

Mr. **Caulder**. Thank you. And I also appreciate the opportunity to be before you today.

Mycogen is a small agricultural company in southern California. We are engaged primarily in the business of developing new products for uses in agriculture. We are entirely research at this point in time. We have not had the good fortune to invent a product that we can put on the market yet. Currently we are concentrating our efforts and our resources, which are primarily research, management and capital, on the invention, discovery, and commercial development of pesticides produced by naturally occurring microorganisms.

Biological control, integrated pest management, balance of nature, pest to control pest, these and many other phrases have been used in the last few years as euphemisms for "how do we reduce the pesticide load on the environment."

With so much time, effort and energy spent looking for these controls, why have they not been very successful in the past?

I think the answer basically is twofold. One is that chemical pesticides such as the pesticides that Monsanto produces have been very good. They are efficacious. They have been cost effective. And they have been safe in the environment.

The second: Biological controls, when compared to chemicals, have been average to poor. Biotechnology, however, or the new science of biotechnology now offers us the tools to improve the efficacy of the biocontrols. And that is basically what we are going to be working in.

Biocontrols offer one thing that is very good, namely the compatability with the environment, by using naturally occurring microorganisms modified to control microbial pests and other pests. The so-called balance of nature approach to biological control has been popular and had a lot of appeal since Rachel Carson's "Silent Spring," published in 1962. The factors limiting this approach have been basically twofold. One is persistance. Biocontrols persist for a very short time in the environment, so they don't do their job very well over a long period of time. This is not very cost effective.

Some chemical controls, however, have persisted too long, DDT and some of the other chlorinated hydrocarbons. And there you have a dilemma.

The second thing has been spectrum of control. Biocontrols generally control one species. They are very specie specific. This, too, is not very cost effective. The problem with chemical controls in this area, they have not been discriminatory enough. They kill a lot of beneficial insects and a lot of desired vegetation. So, now with biotechnology we have an opportunity to approach biocontrol with an entirely new perspective on these two areas of persistance and on spectrum of control.

Chemical pesticides, however, will remain the stalwarts of pest control for the foreseeable future. The new biology will allow us to fill gaps that aren't currently being filled by current chemicals and will allow us to go into those areas that have some ecological sensitivity. Therefore, the future of microherbicides and microbial pesticides will continue to grow, but we will only do it as we are able to show that they are effective and cost effective.

The benefits of this type of research will be manifested, I believe, in two ways: a greatly reduced load on the environment by a reduced use of chemical pesticides, and an entirely new and novel way to control pests which currently destroy or inhibit the products and productivity of about 25 to 40 percent of all the food that is currently produced.

What can keep this progress and this science from progressing? One is failure to establish and protect the intellectual property rights that come with this. Small companies can only survive and compete with large companies like Monsanto and DuPont by working smarter, with less bureaucracy, and investing our limited capital into intellectual assets rather than fixed assets.

We recently dedicated a $3,000 swinging rotor bucket rather than a $150 million building. And we celebrated with beer rather than champagne, I might add.

To us, our assets are intellectual. We need some assurances that as we develop these sciences that we will have some type of protection for him. We must be assured that the value of our ideas and discoveries are protected in some manner.

Second is capricious, tentative or onerous regulations. We have no problems with the concept that our products and science should be regulated. We do have a problem with the time that it may take with onerous regulations. Time is the thing that works against small companies because it costs us money. We have an end point in our capital. We can see it coming because we know what our burn rate is each month. We agree with the concept of reasonable regulations, and we have no problem abiding by these regulations. But we think we should know what the game plan is before we go into it, and as they change, as we continue to develop, that is when we have problems, when we cannot predict what it is going to cost us.

Thank you very much.

[The prepared statement of Dr. Caulder follows:]

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619 453 8030

Mycogen is an agricultural products company. We are engaged in the business of developing new products for use in agriculture. Currently we are concentrating our resources and efforts (research, management and capital) on the invention, discovery and commercial development of pesticides produced by naturally occurring microorganisms.

Biological Control, Integrated Pest Management (IPM), Balance of Nature, Pest to Control Pest - these and many other "catch phrases" have been used as euphemisms for "how do we reduce the chemical pesticide load on the environment."

With so much time, effort and money spent looking for biological controls, why have none been overly successful and so few moderately successful?

The answer is twofold - 1) chemical pesticides have been very good, and 2) biological controls, when compared to chemicals, have been average to poor. Biotechnology now offers the tools to increase the efficacy of biocontrols while retaining their desirable characteristics - namely, compatibility with the environment by using naturally occurring microorganisms modified to produce microbial pesticides.

The so-called balance of nature approach to pest control has had popular appeal since Rachel Carson's "Silent Spring". The factors limiting this approach are twofold, 1) Persistence - biocontrols don't last long enough vs. chemical pesticides which many times last too long - e.g., DDT, and

2) Spectrum of control - not broad enough to be economic vs. chemical pesticides which are too broad either killing beneficial insects or desired vegetation.

Chemical pesticides will remain the stalwarts of pest control for the foreseeable future. However, biotechnology now permits the researcher to address the two major problems (persistence and spectrum) with biocontrols in a direct manner. Therefore, in the future the use of microbial pesticides (biocontrols) will continue to grow in a direct relationship with increased efficacy.

The benefits of this type of research will be manifested in two ways: 1) A greatly reduced load on the environment by the reduced use of chemical pesticides, 2) An entirely new and novel way to control pests which currently destroy or inhibit the production of 25% to 40% of all food products.

What can keep this science from progressing? 1) Failure to establish and protect "Intellectual property rights." Small companies can only survive and compete with large companies by working smarter, with less bureaucracy and investing our limited capital into intellectual assets rather than fixed assets. We must be assured that the value of our ideas and discoveries are protected. 2) Capricious, tentative or onerous regulations. We have no problems with the concept and the need to regulate the products and processes of biotechnology.

There is no need, however, to regulate the science of biotechnology. The regulation of the products and processes should be flexible enough to allow for the advancement of knowledge.

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Dr. Caulder is president and chief executive officer of Mycogen Corporation which is involved in the research and development of genetically engineered microbes to produce pesticides - primarily insecticides and herbicides. Before joining Mycogen Corporation, he spent fifteen years with Monsanto Company.

Dr. Caulder managed Monsanto's agriculture businesses in Latin America for several years and held various research and development positions. His management experience has been about equally divided between research and development and business.

Dr. Caulder holds a Ph.D. in Physiology from the University of Missouri. His formative years were on a cotton farm located in the "bootheel" of Missouri. He still owns and manages the family farm.

Mr. **Brown**. Dr. Caulder, did you leave Monsanto on good terms with Dr. Marvel?

Mr. **Caulder**. Well, I hope so. I think Jack can answer that better than me.

Dr. **Marvel**. I think he left on good terms.

Mr. **Brown**. Dr. Fox, would you like to proceed?

Mr. **Fox**. Thank you kindly, Mr. Chairman.

In 1981 I left Washington, where I was director of the cell biology program for the National Science Foundation, to join the Atlantic Richfield Co. I had expected to return to my duties as professor at the University of Kansas, but instead I found myself in the San Francisco Bay area charged with setting up a new unit of the company which has come to be known as the ARCO Plant Cell Research Institute.

We are a group of some 100 scientists, technicians and support staff engaged in the application of new biotechnology toward the improvement of crop plants. As is well known, during the last few years a series of really unprecedented discoveries in molecular biology has led to an incredible set of new tools now available to biomedical and agricultural scientists. We are making use of these new techniques in recombinant DNA and tissue culture in support of the agricultural activities of ARCO and our seed companies.

When the institute opened its doors some 3½ years ago, no one had successfully transferred a single gene from one higher plant to another and expressed it in the recipient, although this work was proceeding rapidly in microbes and animals. The sad truth is that the plant sciences and the agricultural area, in general, have lagged considerably behind the biomedical sciences in the fundamental discoveries which have led to our ability to genetically engineer microorganisms.

The reasons for that lag are complex, but with apologies to my friends and colleagues at USDA, I think much of the blame must be laid squarely at the feet of the USDA, which never until quite recently felt a mandate to support the basic plant sciences, especially molecular biology, in the same way that NIH supported long-range studies in the biomedical area.

Now, this lack of adequate support for basic research has finally caught up with us. We now find ourselves in the curious position of having the tools for gene transfer in the tool box but not knowing enough about the basic biochemistry and molecular biology of crop plants to make good use of the tools we have. Dr. Marvel already referred to that lag.

We at ARCO, though, regard this state of affairs as an opportunity as well as a detriment. Since many of the basic discoveries in the molecular biology of processes important to crop plants such as disease resistance or drought tolerance are yet to be made, then great opportunities exist for the private sector to establish proprietary positions which could be crucial for success in this business in the long-term. Obviously, companies must position themselves to take advantage of these opportunities, and this means, at the very minimum, having a long-term focus to their R&D efforts and a way of staying current in a field which is changing unbelievably rapidly.

Our approach to this problem at the institute is, first, to provide a university-like atmosphere and then to engage in a mix of long-range and short-term projects. We have already seen unexpected applications arising from studies having a very basic nature.

Second, we have a group of some 25 2-year postdoctoral associates who then go out to academia or other companies, USDA. And we have as well several visiting scientists on sabbatical leave from all over the world who bring in the latest techniques and ideas. We pay our dues by encouraging the publication in scientific journals of all results which are not clearly proprietary.

The research institute model that I am describing is one that is rapidly gaining favor in industry and is in effect forced on us by the unique situation in plant molecular biology. The state of the art is such in this newly developing application of genetic engineering to crop plants that many large companies such as Dupont and Monsanto have apparently concluded that they, too, must do considerable basic research in house, and indeed they too. The net effect of this flurry of activity on the part of industry over the last 3 years has been to dramatically change the focus of research in the plant sciences in this country. No longer is the center of activity in this sphere located in the universities, or at least not exclusively in the universities. Many of the most important new discoveries in plant genetic engineering, even the very basic ones, are being announced by teams of scientists at industry or sometimes university-industry cooperatives.

I am right now in the middle of a conference in Keystone, CO, where some very interesting new discoveries were just announced by people from the Monsanto Corp.

An additional reason for this shift of basic research to industry has to do with the increasingly complex nature of the field itself. No longer is a single individual able to command the intellectual or financial resources necessary to make big leaps in this field. Instead, multidisciplinary teams bringing a diverse set of skills to the solution of a single problem represents a model rapidly becoming the norm. Gene cloners and sequencers are working hand in glove with organic chemists, tissue culture specialists, geneticists and plant breeders on any given project.

What is interesting to me is that the team approach is diametrically opposed to the traditional university ideal. Granting agencies and university administrators reward individual achievement. To be sure, a university scientist may have large groups of associates, but they tend to surround themselves with like-minded postdocs and graduate students.

Collaborations where the credit is unclear or greatly diluted are subtlety discouraged by a set of signals obvious to anyone in the field. The highly departmentalized structure of the university as well as the physical plant itself generally mitigate against the interdisciplinary approach.

The combination of events I have described above and perhaps others as well have led to an exodus of outstanding plant scientists from the university into private industry. This move is not necessarily bad, and indeed I think it will be healthy in many respects for the agricultural sciences as a whole. Nevertheless, such a shift in the way science is being carried out will undoubtedly have considerable impact on activities in this country of concern to this committee.

The universities have a considerable natural resource in the excellence of their staffs built up over a period of many years. I believe it to be in all of our interests to restructure the support of the basic sciences in this country so as to encourage considerably greater activities of research teams within the university setting rather than individual laboratories. At the same time, I hope that the House committee will find ways to foster greater cooperation between the public and the private sector in order that the strengths of each may be fully utilized in our attempts to provide the farmer with bigger and better crop plants.

I won't have time to discuss it here, but the written part of my comments describe several scientific areas related to agriculture in which the new biotechnology is, in my opinion, likely to have major impact.

Thank you.

[The prepared statement and biographical sketch of Dr. Fox follow:]

Atlantic Richfield Company

Testimony on Current Advances in Biotechnology Research

My name is J. Eugene Fox. I am Director of ARCO Plant Cell Research Institute, an operating unit of Atlantic Richfield Company. I appreciate the opportunity to testify today on the current advances in biotechnology research at ARCO.

In 1981, I left Washington where I was Director of the Cell Biology Program for the National Science Foundation to join the Atlantic Richfield Company. Although I had expected to return to my duties as Professor at the University of Kansas, instead I found myself in the San Francisco Bay area charged with setting up a new unit of the Company which has come to be known as the ARCO Plant Cell Research Institute. We are a group of some 100 scientists, technicians and support staff engaged in the application of new biotechnology toward the improvement of crop plants. As is well known, during the last few years a series of unprecedented discoveries in molecular biology has led to an incredible set of new tools now available to biomedical and agricultural scientists. We are making use of these new techniques in recombinant DNA and tissue culture in support of the agricultural activities of ARCO which includes the ARCO Seed Company.

When the Institute opened its doors some 3 1/2 years ago, no one had successfully transferred a single gene from one higher plant to another and expressed it in the recipient although this work was proceeding rapidly in microbes and animals. The sad truth is that the plant sciences and the agricultural area in general have lagged considerably behind the biomedical sciences in the fundamental discoveries which have led to our ability to genetically engineer organisms. The reasons for that lag are complex, but much of the blame must be laid squarely at the feet of the USDA which never felt a mandate to support the basic plant sciences in the same way that NIH supported long range studies in the biomedical area. This lack of adequate support for basic research has finally caught up with us. We now find ourselves in the curious position of having the tools for gene transfer in the toolbox but not knowing enough about the basic biochemistry and molecular biology of crop plants to make good use of the tools we have.

However, we at ARCO regard this state of affairs as an opportunity as well as a detriment. Since many of the basic discoveries in the molecular biology of processes important to crop plants such as disease resistance or drought tolerance are yet to be made, then great opportunities exist for the private sector to establish proprietary positions which could be crucial for success in this business in the long term. Obviously, companies must position themselves to take advantage of these opportunities, and this means at the very minimum having a long term focus to their R&D efforts and a way of staying current in a field which is changing unbelievably rapidly. Our approach to the problem at the Institute is first to provide a university-like atmosphere and to engage in a mix of long range and short term projects. We have already seen unexpected applications arising from studies having a very basic nature. Secondly, we have a group of some 25 two year postdoctoral associates and several visiting scientists on sabbatical leave from all over the world who bring in the latest techniques and ideas. We pay our dues by encouraging the publication in scientific journals of all results which are not clearly proprietary.

The research institute model that I am describing is one that is rapidly gaining favor in industry and is in effect forced upon us by the unique situation in plant molecular biology. The state-of-the-art is such in this newly developing application of genetic engineering to crop plants that many large companies, such as DuPont and Monsanto, have apparently concluded that they too must do considerable basic research in-house. The net effect of this flurry of activity on the part of industry over the last three years has been to dramatically change the focus of research in the plant sciences in this country. No longer is the center of activity in this sphere located in the universities. Many of the most important new discoveries in plant genetic engineering, even the very basic ones, are being announced by teams of scientists in industry or sometimes university-industry cooperatives.

An additional reason for this shift of basic research to industry has to do with the increasingly complex nature of the field itself. No longer is a single individual able to command the intellectual or financial resources necessary to make big leaps in this field. Instead multi-disciplinary teams bringing a diverse set of skills to the solution of a single problem represents a model rapidly becoming the norm. Gene cloners and sequencers are working hand-in-glove with organic chemists, tissue culture specialists, geneticists, and plant breeders on any given project. The team approach, however, is diametrically opposed to the traditional university ideal. Granting agencies and university administrators reward individual achievement. To be sure university scientists may have large groups of associates but they tend to surround themselves with like-minded post-docs and graduate students. Collaborations where the credit is unclear or greatly diluted are subtly discouraged by a set of signals obvious to anyone in the field. The highly departmentalized structure of the university as well as the physical plant itself mitigates against the interdisciplinary approach.

The combination of events I have described above (and perhaps others as well) have led to an exodus of outstanding plant scientists from the university into private industry. This move is not necessarily bad and indeed will probably be healthy for the agricultural sciences as a whole. Nevertheless, such a shift in the way science is being carried out will undoubtedly have considerable impact on activities in this country of concern to this committee. The universities have a considerable natural resource in the excellence of their staffs built up over a period of many years. I believe it to be in all of our interests to restructure the support of the basic sciences in this country so as to encourage considerably greater activities of research teams within the university setting rather than individual laboratories. At the same time, I hope that the House Committee on Science and Technology will find ways to foster greater cooperation between the public and the private sector in order that the strengths of each may be fully utilized in our attempts to provide the farmer with bigger and better crop plants.

Let me now turn my attention to areas of agriculture on which the new biotechnology is most likely to have an impact. In the following, I would also like to consider some fields which have attacted a good deal of attention and press but which are not, in my view, good candidates for serious consideration.

1) NITROGEN FIXATION

We all have heard more hype and hoopla surrounding this subject than in any other area of plant biotechnology but I personally do not know anyone who seriously contemplates getting rich by transferring nitrogen fixing ability to corn plants. In my view, research on nitrogen fixation should be done in the universities; there are still enormous veins of scientific gold to be mined in these diggings. But the notion of transferring the 100 or more genes involved in the process itself, not to mention the genes involved in the energy rich, oxygen depleted microenvironment created by plant tissue structures boggles the mind. One must also consider the tissue and temporal specificity involved in the regulatory apparatus for each gene, as well as the energy cost to a plant and the probable effect on yield (although I am aware that ways to recycle the hydrogen produced in the process rather than dumping it are being looked at). In my view, genetically engineered nitrogen fixers and decades from realization.

2) IMPROVED STRAINS OF MICROORGANISMS

A few companies are actively working towards the improvement of Rhizobium by traditional selection procedures or recombinant DNA technology. Although some positive effects on yield have been claimed when new types have been used for inoculation of plants growing in sterile soil, I know of no evidence to suggest that any such improved strains are effective under field conditions. One might expect that the boys already on the block, the survivors of stringent selection pressures in the soil environment, would have very little trouble in competing with a newcomer. So unless you want to talk about herbicides which also kill all the microflora before introduction of a new strain, then I would rather bet my money in other areas, perhaps on extending the host range of already well adapted nitrogen fixers such as the actinomycete, Frankia.

3) CONVERSION OF BIOMASS TO ENERGY

If you do your homework on the costs of converting plant material to ethanol or methanol, you come away realizing what marvelous packages of energy we have in petroleum and coal. The mathematics on this point are very clear: There is no way that ethanol from grain or methanol from wood chips can compete with petroleum as a source of energy until the price of oil increases substantially (perhaps by a factor of two or three). Even then our several centuries supply of coal would be a cheaper form of energy. Of course, local or political considerations resulting in government subsidies such as we see in Brazil can produce an artificially competitive environment. But I would not bet on seeing a successful application of the new techniques in biotechnology in the conversion of renewable resources to energy in the next ten years.

4) PLANTS AS A SOURCE OF CHEMICALS

I keep hearing from my friends in the chemical industries that the enormous expertise we have in synthetic organic chemistry and process engineering for large scale production makes it very unlikely that plants themselves could ever serve as the original source of commodity chemicals. And, of course, that point of view ignores the fact that most commodities on the world market today are of plant origin ranging from foodstuffs themselves, through fibers, oils and waxes, etc. However, I believe that the real change in the long term will be the penetration of specialty chemical markets by compounds derived from plant sources. Apart from medicinals, plants are a largely untapped source of exotic compounds. I fully expect in the long term to see, for example, new herbicides which have their origin in the so-called allelochemicals by which some plants compete for living space or perhaps in the toxins synthesized by some plant pathogens. Once we are tipped off to chemical structures which have important biological activity, as for example the insecticidal activity of the plant pyrethroids, then even more effective synthetic analogs can be made as Sumitomo and other chemical companies have done. Flavors and fragrances, food additives, new lipids and steroids, insecticides, polysaccharides, etc. all are examples where plant derived substances will have great market impact in the long term. Recombinant DNA technology may make a difference here especially if we can use gene amplification techniques to greatly increase the level of desired products in plants.

5) PLANT DISEASE RESISTANCE

The geneticists and plant breeders have taken us a long way in the field, but the species barrier has until recently always stood in the way of widespread utilization of genes for disease resistance. The new recombinant DNA techniques make it almost certain that in the long term we will be able to move nearly any gene from one plant to another even where the recipient is not closely related to the donor. The area with perhaps the greatest long term economic potential for gene transfer technology is, in my view, disease resistance. Some plant breeders tell us that with certain crops such as hybrid corn the genetic variability for further yield increase may not exist and that we may be coming up against theoretical barriers. I do not really believe that is the case, but even if it were true, I point out that increased resistance to disease amounts for all practical purposes to an increase in yield. Five to ten years down the road, I expect the molecular biology of plant disease resistance to be the hottest single area in the spectrum both scientifically as well as commercially. I know that many share this idea with me since I observe a number of companies beginning to position themselves in this area. The techniques for substantial breakthroughs are here or else just on the horizon and the ideas are beginning to buzz all around us. If I were a beginning young scientist today, there is not doubt in my mind but that this is the area I would jump into.

6) PLANT HORMONE MOLECULAR BIOLOGY

I fully expect to see an explosion in our knowledge and application of plant hormones in the five to ten year vista. The new recombinant DNA techniques give us for the first time the ability to do something truly useful with the plant hormones. Over the last 50 years, plant physiologists have dreamed of increasing plant yields by the judicious application of plant hormones but this work has by and large been tremendously disappointing. In most situations the plant, as a whole, already makes plant hormones in optimum amounts; spraying more on from the outside rarely does anything good, although we know that the growth of certain tissues and organs could be altered in desirable ways with some plant hormones. Recombinant DNA techniques give us, for the first time, the chance of altering the endogenous expression of plant hormones in ways which may have important crop applications. In addition, we are finally beginning to pin down receptors for some of the plant growth regulators and to understand their function at the molecular level. I am beginning to hear rumblings out there which indicate that the plant growth hormone area may burst out on the commercial and scientific scene once again in a big way. I do not expect this renaissance to happen in the next year or two since a good deal more basic research remains to be done. But in the longer term, I believe that the plant hormone field will live up to its long overdue promise in agriculture.

7) THE MOLECULAR BIOLOGY OF STRESS

A considerable amount of work on this subject is currently under way and I expect this item will pop up on the menu of most groups in the private sector workingin agriculture or plant molecular biology. We hear a lot about heat shock proteins, tolerance to osmotic stress or drought, phytoalexins turned on in the face of disease, etc. But frankly, I believe this field to be a perfect example of a point I made earlier. We have already clones of heat shock proteins without the foggiest notion of what they do in biochemical terms to protect plants from heat stress. The limiting factor here, once again, is not the molecular biology but the biochemistry and physiology. It is hard to overestimate the potential of this field for agriculture, no doubt accounting for all of the work going on already. But in my view, stress molecular biology is not a field ripe for commercial exploitation at the moment. In the next three to five years, I expect us to learn a considerable amount of new information at the basic science level concerning the ways in which organisms respond to stress and to identify key points, perhaps enzymes, or metabolic pathways crucial to this response. The great impact of this field in an applied sense is, in my view, likely to come roughly 5 to 10 years down the road.

CURRICULUM VITAE
J. EUGENE FOX

Born: 7 August 1934

EDUCATION

Indiana University, B.S., Biology, June 1956

Indiana University, Ph.D., Plant Physiology and Biochemistry, Sept. 1960

University of Wisconsin, Postdoctoral, Plant Biochemistry, 1961

PROFESSIONAL APPOINTMENTS

1957	Teaching Assistant, Marine Biological Laboratories, Woods Hole, Mass.
1960	Postdoctoral Fellow, University of Wisconsin, Madison
1961	Assistant Professor, Departments of Biochemistry and Botany, University of Kansas, Lawrence
1964	Associate Professor, University of Kansas, Lawrence
1967	Assistant Dean, College of Liberal Arts and Sciences, University of Kansas
1968	Professor, University of Kansas
1968	Visiting Scientist, Department of Biochemistry, University of British Columbia, Vancouver.
1969	Associate Dean, College of Liberal Arts and Sciences, University of Kansas
1972	Visiting Scientist, Department of Biochemistry, Roche Institute of Molecular Biology, Nutley, N.J.
1974	Chairman, Department of Botany, University of Kansas
1975	Visiting Scientist, Department of Biochemistry, Rothamsted Research Station, Harpenden, England
1979	Director, Cell Biology Program, National Science Foundation, Washington D.C.
1981	Director, ARCO Plant Cell Research Institute, Dublin, California

PROFESSIONAL ORGANIZATIONS

American Society of Biological Chemists, American Botanical Society, American Society of Plant Physiologists, Scandinavian Society for Plant Physiology, Japanese Society of Plant Physiologists, American Association for the Advancement of Science Society of the Sigma Xi

SCIENTIFIC PUBLICATIONS

Fox has some 50 publications including articles in scientific journals, chapters in texts and one book. He is the holder of several patents dealing with plant growth promoting hormones.

REPRESENTATIVE PUBLICATIONS

Fox, J. E. and C.M. Chen. 1967. Characterization of labelled ribonucleic acid from tissue grown on ^{14}C-containing cytokinins. J. Biol. Chem. 242:4450-4454.

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Keim, P. and J. E. Fox. 1980. Interaction of a radiolabeled cytokinin photoaffinity probe with a receptor protein. Biochem. Biophys. Res. Commun. 96:1325-1334.

Brinegar, A.C., and J.E. Fox. 1984. Resolution of the subunit composition of a cytokinin-binding protein from wheat embryos. Biol. Plantarum (in press).

CONSULTING ACTIVITIES

Fox has consulted for a number of corporations including Monsanto and Dupont. He also consulted extensively for the Ford Foundation and the Interamerican Development Bank and made many trips to South America in support of programs funded by these agencies. In addition he has consulted extensively for the educational programs of a number of U.S. Universities including the University of Texas, Louisiana State University, University of Wisconsin, Iowa State University, The State University System of Oregon and others.

Mr. **Brown**. Thank you very much, Dr. Fox.

I find the testimony of all of you gentlemen extremely interesting and significant with regard to the developments in this very important new field. I want to express my appreciation to you for the contributions that you have made here this afternoon.

Mr. Volkmer?

Mr. **Volkmer**. Yes, I just wish I had a better voice.

I think you raise some questions. In fact, I am very tempted to ask the chairman to bring Dr. Bentley back to the table again, but maybe we can ask some questions in writing. I am sure we will have some, Dr. Bentley—I see he is still in the audience—in regard to this.

I find, Dr. Marvel, and Dr. Fox alluded to it, too, more research in plant biochemistry, plant physiology and molecular genetics. That to me are basics. As Dr. Fox, I think, elaborated on that and said we don't know the basics about many of our plants to even—in other words, we have got the tools but we don't know what it's all about to work with the tools.

Do you envision that the university area would be the area where that type of basic research should be done?

Dr. **Marvel**. Well, I think that there are two things. Dr. Fox also mentioned that that is changing now. Industry is forced into a position where it has to. I guess, from a strategic position for the country—and I don't have good number, so, for Pete's sake, don't put them in the record—but I think the country has probably spent, I don't know, in the range maybe of $100 billion on fundamental research related to health since 1940, just a wild guess. I suspect that the number in fundamental research in plants and maybe agriculture, but in plants, might be $100 million.

Now, you know, from a science point of view in terms of data that you have generated, I think Mr. Brown said this earlier, the reason for our advances in that health field are because we have spent that money. Agriculture has got to be proportionately less known for that reason.

Now, I don't think any of us would probably tell you you have to spend $99 billion, or whatever, to get to that point, but I think you have to spend a significant slug of it to get it. And I think the issue for the Nation is, if you're going to be cost-competitive in agriculture in the world, you are faced with trying to decide where American agriculture is going to be, because somebody in the world is going to take advantage of that market. That would be my perception anyway.

Mr. **Volkmer**. Dr. Fox, would you agree basically with that? Do you have a comment?

Mr. **Fox**. I agree with what Dr. Marvel had to say. I think there is no question but that we are clearly ahead as a country in terms of our understanding of molecular biology in both plants and animals. But our position in the animal and microbial field is considerably further ahead of other countries than it is in plants.

For example, England has a substantial amount of basic knowledge about plant molecular biology which is very, very close to ours, in some areas even slightly ahead. But I think that reflects the relative commitment of resources to those areas that we have seen in this country and in England.

Mr. Volkmer. Dr. Fox, earlier we had testimony from USDA officials about the center that was being established in the bay area. I believe ARCO was mentioned as one of those who will be cooperating with that. Do you find that that center to be a thing that will help focus on the total biotechnology field?

Mr. Fox. Absolutely. I think it is one of the most encouraging things that USDA has done in recent years. I do believe it is too little and somewhat too late. But, I mean, they have, what, a couple of million dollars? I think that is a small amount of the money that one requires to have a significant commitment for an operation like the USDA in this field. But nevertheless, we hope that, once that institute is formed and is set up, that we will be able to work closely with them.

Mr. Volkmer. Without trying to get into anything that is proprietary or anything like that—maybe we can get it this way. The ARCO budget for where you are operating in the bay area, would it be in excess of the amount that USDA will be spending on their center?

Mr. Fox. Our budget is roughly four to five times that every year.

Mr. Volkmer. Mr. Marvel, Monsanto's budget, you mention on total is about $100 million a year. But how much would be on the biotechnology or recombinant DNA?

Dr. Marvel. Well, it would depend a little on your definition, but you could probably place almost up to a third of it in that area.

Mr. Volkmer. Very good.

And, Dr. Caulder, it appears that probably about every bit of your budget is totally in the research into this area?

Mr. Caulder. Yes, I would say that—the way a small company can compete with a Monsanto is that we have very little overhead. When Jack talks about his dollar, every dollar I spend is for product development. So, when I look at the large budgets that ARCO and Monsanto have, I am envious but I am not intimidated too much by them.

Mr. Volkmer. I would like to mention, yes, Dr. Fox, we plan later on in one of our hearings to discuss and have some witnesses on the international research being done and in the national area also.

Oh, yes, Dr. Fox and Dr. Marvel, do you in your industry-university cooperation have any agreements with land-grant colleges?

Dr. Marvel. Let's see. The answer to your question is yes. I am trying to think of——

Mr. Volkmer. In other words, Iowa or Iowa State, I mean, and the University of Missouri or Kansas State or any——

Dr. Marvel. Yes, we do have some——

Mr. Volkmer [continuing]. Other than private?

Dr. Marvel. Yes, we have agreements with both Iowa State and the University of Missouri, among other things, as well as—I can't tell you off the top of my head how many universities, but there is a large number. The biggest and best-known biotechnology grants in Monsanto probably are to Washington University, which is private, Rockefeller University, Oxford, and Harvard. But those are largely—well, they are not heavily into the ag field, for example, except the one at Rockefeller. And a lot of the ag field's work we do goes across many land-grant universities in this country that have expertise in certain areas of plant science.

Mr. VOLKMER. Dr. Fox, does ARCO?

Mr. FOX. We don't have any research that we fund out in the universities. The reason for that is that we worry about the ethical considerations. But we do have a number of informal research projects going on between university scientists and people in our institute. We publish jointly with university scientists.

In addition, we have funded a number of graduate fellowships up and down the west coast on a no-strings-attached basis.

Mr. VOLKMER. That was the next question. I am glad you got that in there. Dr. Marvel, that's what I was asking about the land grants especially, on the question of proprietorship, that if there is something significant determined, is it permitted to be published in your arrangements with the land-grant colleges?

Dr. MARVEL. It depends on case by case. In a philosophical sense, I would agree with Dr. Fox, to the extent that you can do it with no strings attached, it makes life much simpler for all parties. Where larger grants of longer duration are involved, there are some specific arrangements with that. But, for example, the Washington University arrangement is such that their ability to publish only can be encumbered for—I have forgotten the exact amount, but I think it is around 6 weeks at the most, while certain patent applications are filed. But basically that right is preserved.

Mr. VOLKMER. Thank you, Mr. Chairman.

Mr. BROWN. Mr. Packard?

Mr. PACKARD. Thank you, Mr. Chairman——

Mr. BROWN. There will be five bells here. Let's let them ring.

[Pause.]

Mr. PACKARD. I think, in view of the time, I will try to hold my questions to a minimum, being we are having a vote called.

First of all, let me welcome Dr. Caulder to our committee. Dr. Caulder comes from San Diego, where I represent. His business is not in my district——

Mr. VOLKMER. Will the gentleman yield?

Mr. PACKARD. Yes, sir.

Mr. VOLKMER. He's a Missourian originally.

Mr. PACKARD. I saw that. I read that carefully. So, I think we can both claim his expertise here. I am grateful that he is here with us.

Let me ask my first question to Dr. Caulder. It relates to chemicals and pesticides as used by farming and farmers. In my area, as you know, in north San Diego County, where there is a significant amount of rather unique farming that takes place, avocados and citrus, and then, of course, winter tomatoes, strawberries, cut flowers, and those things that are a high cash crop are significantly impacted by foreign markets, particularly because of, well, a variety of reasons. One, of course, is subsidies of foreign governments of their own commodities and making it more difficult for our farmers to compete.

Another problem we have run into is the use of chemicals and pesticides in foreign markets that are not permitted by our own farmers. That is very true in San Diego County, where they raise tomatoes. Just across the border, not more than 50 or 60 miles away, below Tijuana, in Baja California, they are raising higher and higher yields of tomatoes there. They are allowed to use chemicals and pesticides that our farmers are not. Yet, we turn around and import across the San Diego border those very same commodities that they raise using the chemicals that our farmers cannot and are not allowed to use.

That, to me, is a significantly unfair trade agreement and arrangement and puts our farmers not only at a disadvantage but they are insensed and don't understand how the United States could implement such a policy. Frankly, I don't know either.

I would like your response, being in the chemical and pesticide business and doing considerable research in that area. Do you think that our regulations and our policies are favoring the American farmer or are they favoring their competitors across the borders?

Mr. CAULDER. I don't know if favoring is the right word. It becomes a matter of cost. When you look at a lot of the crops in California, which has what would be considered in the eyes of Dr. Marvel and Dr. Fox minor crops, tomatoes being one of them, it takes the same amount of money to develop a product for tomatoes that it does for corn, which you have 80 million acres in the United States. So, when you are setting your priorities and when they are justifying their budgets to their respective managements, it makes a lot more sense to talk about developing new products where the market is 80 million acres than a few hundred thousand acres, especially when the invention development costs are exactly the same.

So, I do think to some extent our regulatory procedures that—and we do have special mechanisms for some of the minor crops and a few of these things that alleviate some of those costs. But it does put us at a slight disadvantage when you can get products cleared in other countries under a more favorable regime of regulation.

Mr. PACKARD. Is there any attempt—incidentally, it's not only the chemicals and pesticides, but you got different grade standards also where they are not required to live by the same grading standards. Perhaps, maybe the question should have been asked the Department of Agriculture, but, nevertheless, I think they understand my concern that there ought to be an enforcement in allowing at our—our imports ought to be as carefully monitored in terms of meeting the requirements that our farmers are required to.

Is there any international standardization of either grades or chemical pesticide controls?

Mr. CAULDER. Certainly not across countries. Within certain countries there are. But in the Latin countries that we are talking about, Mexico and south, very little regulation of any of those things.

Mr. PACKARD. OK. Let me ask one question to Dr.—I believe it's Dr. Marvel in his testimony. It was indicated that we are having an exodus of outstanding plant scientists from the university to the private sector. Maybe that was Dr. Fox.

I was wondering, in your judgment are we losing that talent? Or are we seeing a transfer of this kind of research from the university level to the private sector?

Mr. Fox. I don't think we are losing that talent for two reasons. The scientists will make a contribution whether or not it's in industry or in university. At the same time, our graduate students—and this was alluded to earlier—are not dumb. They know where the action is. We see an enormous number of students now beginning to transfer into the plant molecular biology area because the jobs are there.

The question was asked in the previous committee about the problem of finding scientists in this area; and having just hired some 50 Ph.D.'s in the area, I can tell you that the plant scientists with the kind of training we would like to have simply aren't there at this point. It is extremely difficult to get these people. There are always a number of scientists who prefer, for one reason or another, to remain in the university setting. And we have seen several examples of this. Those people will continue to turn out good students who will come into the area in the future.

So, while we have a problem right now, I don't anticipate that 5 years down the line there will be a similar problem in this area. People are moving into it rapidly.

Mr. Packard. No other questions, Mr. Chairman.

Mr. Brown. Gentlemen, I am going to ask a couple of questions, and then I am going to excuse you because we may be in recess for voting for perhaps 15 or 20 minutes. I don't want to keep you here unnecessarily.

The problem that we are just discussing here with regard to the flow of university scientists into industry in this field, this could be construed as a healthy situation in the sense that the scientists, if what you say is true, may be working in an environment, an interdisciplinary environment frequently with better research facilities than they have in the university. The productivity might actually increase as a result of that. Is that not true?

Mr. Fox. I believe that to be true. I was in a university setting for nearly 20 years. I think there is no question but that I am able to do more good science in industry now than I was at the university.

Mr. Brown. Having visited some of the industry labs, including Dr. Marvel's, I had the feeling, at least in the better ones, there was a tremendous amount of opportunity and creativity.

Mr. Volkmer. Would the gentleman yield?

Mr. Brown. I would be glad to.

Mr. Volkmer. In that regard, I believe that during your original statement—your comment of what I view, because it is going to be what I address my written question to Dr. Bentley on, viewed that you would like to see even in the university research a change made in the methodology in which research is done in this field. Is that correct or incorrect?

Mr. Fox. I think it would be very healthy if grants were made in a way that could recognize team efforts rather than individual——

Mr. Volkmer. Individual efforts?

Mr. Fox. Yes, sir.

Mr. Volkmer. Do you agree with that, Dr. Marvel?

Dr. **MARVEL**. Yes. In fact, we have made suggestions either through the advisory board or other places that it would be very helpful in the competitive grant area if you could structure grants that would favor interdisciplinary actions, yes.

Mr. **VOLKMER**. Thank you.

Mr. **BROWN**. I appreciate your bringing that up, Mr. Volkmer, because that was going to be the next point that I raised. The effect of what you are doing in the competitive nature of the activities may be beneficial in improving the conduct of university science and the restructuring of university science, hopefully, improving the environment in universities. And we will all benefit from this competitive situation that would exist.

Dr. Fox, you indicated that you weren't too much involved in joint or cooperative research with universities. Is that a matter of deliberate policy based upon the ethical considerations that you raised? Or are you in a position where you are still forming long-range policy in this regard?

Mr. **FOX**. I think I said that we didn't fund research in universities. We are certainly involved in an enormous amount of cooperative programs with universities, but these are all on an informal, that is, an unsigned basis, doing science.

In terms of our policy not to award research contracts to universities, yes, that was a deliberate policy that we formulated at the outset because we thought it would entangle us in situations that would be unhealthy for both universities and for the industry.

Mr. **BROWN**. Well, we may want to explore that with you a little bit more sometime.

I am going to call a recess at this point and excuse you gentlemen. When we return, I would like to have our two final witnesses at the table so that we can expedite the time at that point.

Again, thank you very much. If you would respond to written questions from the staff, we would appreciate it very much.

The subcommittee will be in recess.

[Recess.]

Mr. **BROWN**. The subcommittee will resume its sitting.

We are pleased to have as our final two witnesses, plus Dr. Fox from the previous panel, Dr. Dick Sauer from the University of Minnesota, replacing Dr. Wood, who is unfortunately ill and could not be here; and Dr. Ronald Knutson, professor of agriculture policy at Texas A&M. We have asked Dr. Fox to continue with us for some additional questions that were raised in the previous panel and perhaps will be raised as a result of the testimony of you two gentlemen who are here representing the land-grant college system.

Dr. Sauer, is that S-a-v or S-a-u?

Dr. **SAUER**. The sign is wrong. It is S-a-u.

Mr. **BROWN**. And "Sauer" is the correct pronunciation?

Dr. **SAUER**. Right.

Mr. **BROWN**. Would you proceed then with your testimony?

STATEMENTS OF RICHARD J. SAUER, DEPUTY VICE PRESIDENT, INSTITUTE OF AGRICULTURE, FORESTRY AND HOME ECONOMICS, DIRECTOR, AGRICULTURAL EXPERIMENT STATION, UNIVERSITY OF MINNESOTA, ST. PAUL, MN; RONALD D. KNUTSON, PROFESSOR AND EXTENSION ECONOMIST, TEXAS A&M UNIVERSITY SYSTEM; AND J. EUGENE FOX, ARCO RESEARCH, PLANT CELL RESEARCH INSTITUTE, DUBLIN, CA

Mr. **Sauer**. Thank you, Chairman Brown and members of the committee. I am delighted to be here.

My name is Richard Sauer. I am deputy vice president for Agriculture, Forestry and Home Economics and director of the agricultural experiment station at the University of Minnesota. I am substituting for Dr. Wood, dean for research in the Institute of Agriculture and Food Sciences at the University of Florida, and chairman of the Committee on Biotechnology for the National Association of State Universities and Land-Grant Colleges.

I am a member of that committee chaired by Dr. Wood. I am responsible for the agricultural and related research programs at the University of Minnesota, which includes some substantial research programs in plant and animal biotechnology. Our own university has a task force which has just released its analysis of issues that relate to university-industry relationships in biotechnology and other areas.

What I will present today is extracted from three progress reports collectively titled "Emerging Biotechnologies in Agriculture, Issues and Policies, of the Committee on Biotechnology," which Dr. Wood chairs. And the key point I am going to focus on today is university-industry relationships. And really the key issue within that theme, I feel, revolves around intellectual property rights. And I will make some more comments on that a little bit later, but I think that becomes a key focus regardless of the mechanisms or the arrangement for the university-industrial partnership.

I would like to start by making the point that the university must protect the public interest. And the people resource or the human resource is the greatest resource of a university: the present one in terms of faculty, and the future one in terms of faculty and graduate students. And integrity of the universities as public institutions of research and higher education must be protected.

There is the issue of credibility, of objectivity, one that we have gained over some time in land-grant universities in more traditional programs that might lead to the development and release of new plant varieties and the testing of both public and private varieties, the testing of agricultural chemicals and many other products and processes where the people have looked to us as a source of objective, creditable information.

Part of the written testimony that was prepared by Dr. Wood and is submitted for the record, I will not go through in detail, but I would like to point out that that testimony includes guidelines for the development of the university-industry research contract. We developed it in our committee as a general guide for the development of a contract between the private sector and research university.

I would quickly point out that not all universities and not all sponsors will be able to utilize every provision in that guide. Universities vary considerably in their own institutional policy, and that needs to be taken into account.

But I would like to emphasize a couple of points relative to that contract. I would first like to quote from two general statements in the contract or the proposed agreement: one with regard to the role of the university, and the other with regard to the role of the industrial sponsor.

The university as a public-supported institution must recognize the importance of its project in terms of it benefiting the general public. It is essential that the universities promote the free flow of information at all stages in research and exist for the advancement of science and technology, and that any agreement with the private sector should not be permitted to compromise the purpose of the university in an unreasonable manner.

On the other hand, we must recognize that the industrial or commercial sponsor has primary objectives which are commercial. The sponsor's purpose as a commercial entity is to develop products, processes, and services for the generation of profits. And any agreement should not be allowed to hinder unreasonably the sponsor's interest in protecting and exploiting intellectual property rights which either have originated with the sponsor or which originate from the research project itself.

Those two considerations are to some extent necessarily conflicting and must be compromised to some extent by each side and to the best interest of the particular needs and the desires of the parties involved. But I think if the differences between the universities and the private sector are recognized and addressed up front during the negotiations, that more effective collaboration can and in fact is taking place, and mutually acceptable contracts are being developed.

I would like to just point out a couple of other areas where we do provide some recommendations or guidelines. We provided some suggested statements with regard to publication, copyrights, and trade secrets. Publication and dissemination of information coming from research at a university are integral to the purpose of that university. The university should be the sole judge of what it will publish and shall have the exclusive right to publish any and all of the results of that research project. On the other hand, we must be sensitive to the needs of the sponsor in terms of any time needed to submit a patent application before publication. We have suggested that in some cases there may want to be a specific time period talked about that would allow adequate time for the industrial sponsor to submit a patent application but not such a long time period that it would unduly delay the dissemination of that new knowledge to the scientific community.

And we have even suggested that from many of our conversations with various universities and participating companies that a 60-day time period might be a reasonable one to think about.

We do make a brief statement about press releases. That, in a sense, relates to what I have just said. That section is really included in order to protect the industrial sponsor from a premature disclosure of vital information.

And then patent rights, per se. We think it is preferable that the universities maintain title to patents which are derived from the research, although we realize that this varies widely amongst universities in this country, and that the sponsor then, the industrial sponsor should receive a right of first refusal to a license on such patents, and return for a reasonable royalty based on the receipts from the products manufactured under such patents.

And in the event that the sponsoring company does not fulfill its obligation to exploit the patent rights, that such patent rights might well revert to the university if the university had not retained them in the first place. In other words, I believe that the university needs to maintain some control to the extent that, if a given product or process is not exploited by the private corporation that is part of the agreement, that the university could then pursue some other route to provide that new technology or new knowledge to the public, with the bottom line being the benefit of the public good.

There have been situations where a company might well enter into an agreement with a university for the purposes of tying up the technology, technology which otherwise might compete with a product that the company already has on the marketplace. And if the university's purpose is to serve the public good, then we might well pursue alternative ways to release that new knowledge because we feel that kind of competition would indeed be healthy.

I would also make a statement relative to termination rights, and I think this again in a sense relates to what I have just said, that it might be the desire of the university to terminate such an agreement if it appears there will be little public benefit to the university programs or to the public from continuing the agreement.

The rest of the proposed contract is in the record.

I would like to switch then to a couple of other brief points. While talking a lot about problems, I must also emphasize that there are surely some advantages of close working relationships between universities and private industry. As Dr. Knutson, who follows me, will point out, in agriculture the extension of information from land-grant universities has been institutionalized in part through State extension services involving local, State, and Federal funding and leadership.

We also recognize that our higher education institutions have generally recognized individuals involved in research may carry on private information disseminating activities within the limits of established policies. I am talking about consulting and other forms of information dissemination that can be viewed within the public interest. The kind of consulting that university scientists enter into can help in accelerating the transfer of information and therefore an earlier realization of the benefits from the research done at the university.

The faculty member who consults in turn perhaps gains a better insight into the problems in the real world and the adequacy of available information for solving those problems. And there are many other advantages as well. At the same time, there are some problem areas that surely merit attention, and the conflicts of interest that arise. We outline in the written testimony three categories of potential problems.

First, those conflicts that may relate to perceptions that outside interests receiving consultation on a private basis are being favored unduly. Second, perceptions that the faculty member may face a conflict of interest in the allocation of his or her professional time or intellectual effort. The university may feel that it is not getting its share of the time of the faculty member. Likewise, the sponsoring company may feel that they are not getting the fair share of the time that they contracted for. And, third, perceptions that intensive consulting arrangements with a single company over a long period of time may lead to nonobjectivity on the part of the faculty member.

We have outlined those issues in detail. I would rather not go into them but respond to questions later.

Finally, I would like to focus on the human resource issue, and you brought it up a little bit earlier in the testimony when you asked questions about the movement of scientists from university to the private sector.

If you go back into the late 1970's and early 1980's I think there was a real fear in the academic community that the intensification of biotechnology research efforts in the private sector would create a demand for human capital, with the consequence that we would have a disproportionate number of scientists dislocating from universities to the private sector. There has been a movement from the universities to industry, especially established individuals at the associate and full professor levels. However, I don't think the worst fears have been realized. In fact, a survey that we did of the State agricultural experiment stations and land-grant universities in 1983 showed that the movement of scientists from our universities to industry was no greater than the movement of our scientists to other universities.

So, in one sense other major universities have been as great a competitor for these outstanding scientists as has the private sector been.

That still, I think, emphasizes the point, and it was made very well earlier by testimony from individuals from the private sector, that at this point in time there are only so many such blue chip scientists, if you will.

Many States, in an effort to attract industry, are creating various biotechnology institutes and centers, each one saying they are going to hire 20 or 30 blue chip senior scientists. Industry wants to hire these same blue chippers. And many universities are going to endow chairs and other kinds of mechanisms to again draw on the blue chippers. And I would suggest right now there are not that many blue chippers to go around.

I suppose if I could use an analogy, it might be the new U.S. Football League and the numbers of blue chippers that can adequately staff those teams alongside the established NFL.

That speaks to the importance of graduate education and particularly in the near future.

I would like to put in, I suppose, one plug for the Competitive Graduate Fellowships Program that was funded in the fiscal year 1984 USDA budget at the level of $5 million. It was cut to $3 million in the 1985 budget. And it is recommended to be zeroed out in the President's executive budget. I think we are talking about a very important investment here. And if you go back and look at the awards from that Competitive Fellowships Program, many of them went to research programs that relate to biotechnology research.

So, I think we need to remember the importance of graduate education. In fact, public support for research in this area is an investment in graduate education and the training of an adequate number of scientists, as much as it is an investment in research per se.

I would make one quick summary statement and then turn to my colleague for his testimony before we respond to your questions.

A variety of mechanisms exists whereby universities and industries may interact in research and development that are mutually beneficial to both parties. And I think there are already numerous examples of successful university-industry cooperative efforts. If future potential cooperative activities are discussed or negotiated in an open environment, where full disclosure of each party's interest and related efforts is made, then we do think workable agreements can be developed without violating the principles and goals of the cooperating institutions or of the industries.

We think sensitivity to the basic issues which I have tried to outline briefly and which are covered in more detail in the submitted written testimony are essential to the development of an effective cooperative relationship. Thank you.

[Additional questions for Richard Sauer for the record; see appendix D, p. 354.]

[The prepared statement of Mr. Wood follows:]

TESTIMONY BY F. ALOYSIUS WOOD

UNIVERSITY/INDUSTRY RELATIONSHIPS[1]

I. Introduction

Research opportunities with high potential economic pay-off involving basic and applied research, which colleges and Universities are uniquely qualified and positioned to provide, place heavy emphasis upon the relationships of the University and University personnel to the research funding agencies. As institutions with somewhat different traditions, cultures and short-run objectives, private business firms and higher education generally share longer-term goals. The development of a knowledgeable and informed citizenry and improvement of levels of living for the entire human family are objectives generally held in common by the private sector and by colleges and Universities.

The transfer of technical knowledge and skill from educational institutions to industry contributes importantly to technological advance which, in the long-run, is generally viewed as beneficial to society. Under the assumption that research is a desirable public good, efforts to reduce the time necessary for such transfers and to expedite the conduct of research within colleges and Universities should be viewed as clearly in the national interest.

II. General Concerns Regarding University/Industry Relationships

Thus, it would appear to be in the general interest to develop principles that can be used to (1) recognize and accommodate the separate motivations of the Land-Grant Universities and potential grantors supporting biotechnological research and (2) to reach compromises allowing the development of mutually acceptable relationships between industry and Land-Grant Universities. Such relationships would need to be based on the ultimate objective of providing maximum public benefit for the Land-Grant Universities to have involvement. Enhancement of public benefit could occur not only through the infusion of major new funds into research, but also through a possible enhancement of the technology transfer process to private enterprise. There are some concerns on the part of the Land-Grant Universities in establishing contractual relationships with profit-motivated elements of industry. The major concerns of the Land-Grant Universities fall into several general categories.

1. As publicly supported institutions, the Land-Grant Universities will need to assure that industrial relationships generate results in the interest of the general public. Industrial investors should be rewarded but not placed in an unwarranted position of financial advantage through privileged use of information or technology partly derived from research using public funds; nor should there be a curtailment of new information to the public.

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[1] Primary Source: Emerging Biotechnologies In Agriculture: Issues and Policies, National Association of State Universities and Land-Grant Colleges, Division of Agriculture Committee on Biotechnology, Progress Reports I (1982), II (1983), and III (1984), F. Aloysius Wood, Chairman, Division of Agriculture Committee on Biotechnology.

2. The Land-Grant Universities are concerned about the curtailment of communication of early research results and about the constraints on sharing of inventions due to concerns on the part of scientists and institutions for protecting patent rights. Industrial sponsorship tends to exaggerate this problem.

3. There is general concern in the academic community about the drain of scientific manpower from the Universities to industry. the ability to continue to conduct basic research in the academic environment and the concurrent interdependent ability to continue educating scientists are the key issues.

4. There is concern that individual scientists may place themselves in positions of compromise or conflict of interest as they establish personal relationships with industry as contractors, consultants or institutional officers.

5. There is a concern on the part of both scientists and the Land-Grant Universities that through industrial sponsorship of research, there may be introduced an undesirable level of direction of effort by industry.

However, close working relationships between University and industry also pose problems that merit attention as arrangements are developed and implemented. In particular, careful attention should be given to protecting the integrity of cooperating Universities as institutions of higher education. Also, in undertaking research on a contractual basis with private research funding sources, problems may arise over the extent to which the public investment previously made should be used in conjunction with contract research activity. These and related potential problems are addressed in the following section which sets out guidelines for developing a contract between University and industry.

III. Guidelines For Development of University/Industry Research Contract

A. Introduction

This guide for the development of a contract is intended to provide the basis for negotiating a cooperative project between a research University and an industrial sponsor. A contract between a University and an industrial sponsor presents many unique policy issues which must be addressed during the initial stages of negotiations in order to arrive at a successful agreement. A University/industry research contract--like any contract--involves the exchange of consideration, i.e., the promise of the sponsor to provide funding or facilities in exchange for the University's promise to use its best efforts to fulfill a research plan. This guide presents sample contract sections with appropriate comments following each section to highlight the most important policy issues and problems and to suggest alternatives. The current tax incentives of the Internal Revenue Code for contributions to research are reflected in the commentary. All Universities and all sponsors will not be able to utilize every provision contained in this guide. A contract of this nature is intended as a guide which must be form-fitted to attain individual objectives and policies of the contracting parties.

B. Memorandum of Agreement

This memorandum of agreement is entered into on ________________ between ______________________________ (the University) and ______________________________ (the Sponsor) for the establishment of a research project entitled, ____, to be conducted from ____________ to ____________ at a total estimated cost of ____________.

COMMENTS--

THE MEMORANDUM OF AGREEMENT SHOULD SET FORTH CLEARLY THE DATES DURING WHICH THE PROJECT SHALL TAKE PLACE. THE PARTIES MAY WISH TO STIPULATE THAT THE DURATION OF THE PROJECT SHALL BE NEGOTIATED AT A LATER DATE. CONDITIONS UNDER WHICH THE PROJECT WILL TERMINATE MIGHT BE INCLUDED ALSO. ONE SUCH CONDITION COULD BE DEATH OF THE PRINCIPAL INVESTIGATOR AND THE INABILITY TO FIND A MUTUALLY ACCEPTABLE REPLACEMENT.

C. General University Purpose

Whereas the University is a publicly supported institution, the parties to this agreement must recognize the paramount importance for this project to benefit the general public. The Sponsor should be rewarded from the results of the research, but it should not be provided a financial advantage through privileged use of information that is wholly or partly derived from the use of public funds. It is essential that the University promote the free flow of information at all stages of research. The University exists for the advancement of science and technology and for the enrichment of education; the research project under this agreement should not be permitted to compromise the purpose of the University in an unreasonable manner.

D. General Purpose of the Sponsor

The parties to the agreement must recognize that the primary objectives of the Sponsor are commercial. The Sponsor's purpose as a commercial entity is to develop products, processes, and services for the generation of profits. On the other hand, it must be emphasized herein that the Sponsor (as well as industry in general) provides intellectual stimulation and interpretation of research that is valuable to the University and to the public in general. This agreement should not be allowed to hinder unreasonably the Sponsor's interest in protecting and exploiting intellectual property rights which either have originated with the Sponsor or which originate from the Research Project itself.

COMMENTS--SECTIONS C AND D

SECTIONS C AND D ARE INCLUDED AT THE OUTSET OF THE CONTRACT IN ORDER TO EMPHASIZE THAT THIS IS A UNIQUE AGREEMENT. THERE ARE IMPORTANT POLICY CONSIDERATIONS THAT SHOULD BE EVALUATED BY BOTH PARTIES BEFORE ENTERING INTO THIS TYPE OF RESEARCH PROJECT. THESE CONSIDERATIONS ARE NECESSARILY CONFLICTING AND MUST BE COMPROMISED TO

SOME EXTENT BY EACH SIDE. ALL THE TERMS OF THIS TYPE OF AGREEMENT SHOULD BE SPECIFICALLY TAILORED TO THE PARTICULAR NEEDS AND DESIRES OF THE PARTIES INVOLVED. A SIGNIFICANT AMOUNT OF VARIATION WILL OCCUR DEPENDING UPON THE VARIOUS POLICIES OF THE UNIVERSITY AND THE SPONSOR. IF THE DIFFERENCES BETWEEN THE PARTIES ARE RECOGNIZED AND ADDRESSED DURING NEGOTIATIONS, MORE EFFECTIVE COLLABORATION CAN TAKE PLACE.

AN AGREEMENT OF THIS NATURE MIGHT BE UTILIZED TO FUND AN ENTIRE RESEARCH PROGRAM, WHICH INCLUDES MANY DIFFERENT PROJECTS.

E. Scope of the Research Project

The research project under this agreement is to consist of ____
____.

COMMENTS--

THIS SECTION CAN BE EITHER VERY BROAD OR VERY DETAILED, DEPENDING UPON THE PARTICULAR PROJECT AND THE DESIRES OF THE PARTIES. THE UNIVERSITY MAY NOT WISH TO DIVULGE GREAT DETAIL WITHOUT SUFFICIENT ASSURANCES THAT THE SPONSOR WILL MAKE PAYMENTS. A CLAUSE FOR MINIMUM PAYMENTS OR FOR PAYMENTS OVER A MINIMUM PERIOD OF TIME MIGHT PROVIDE A WORKABLE SAFEGUARD. THE SPONSOR MAY WISH TO BE INFORMED OF THE EXACT SCOPE AND PARAMETERS OF THE PROJECT IN ORDER TO MEET ITS NEEDS AND TO ASSURE THAT ITS FUNDS ARE NOT DIRECTED TOWARD NEEDLESS OR FRIVOLOUS INVESTIGATIONS.

WHERE THE SPONSOR IS GRANTED BROAD OR DIRECT RIGHTS TO INTELLECTUAL PROPERTY WHICH IS DERIVED FROM THE RESEARCH PROJECT, OR WHERE EXCLUSIVE FUNDING CLAUSES ARE INVOLVED, IT IS DESIRABLE TO DESCRIBE THE RESEARCH PROJECT IN AN ATTACHMENT TO THE BASIC AGREEMENT. IN THIS CASE, A SUGGESTED SCHEME WOULD BE TO DEFINE THE RESEARCH PROJECT AS NARROWLY AS POSSIBLE AND PROVIDE A FRAMEWORK BY WHICH TO REVISE THE DIRECTION OF THE RESEARCH BY MUTUAL CONSENT OF THE PARTIES. THESE REVISIONS SHOULD BE DESIGNED TO LEAVE THE TERMS OF THE BASIC AGREEMENT INTACT. IN THE EVENT A PATENT OR OTHER PRODUCT OF RESEARCH RESULTS FROM MORE THAN ONE SOURCE OF FUNDING--EITHER BECAUSE OF SUCCESSIVE OR OVERLAPPING PROJECTS--A DETAILED AND SPECIFIC DESCRIPTION OF THE RESEARCH TO BE CARRIED OUT UNDER THE AGREEMENT WILL HELP TO AVOID ANY CONFLICTING CLAIMS TO SUCH PROPERTY. PROGRESS OF THE RESEARCH SHOULD BE REVIEWED PERIODICALLY, ALLOWING BOTH THE UNIVERSITY AND THE SPONSOR TO RECOMMEND CHANGES IN THE SCOPE OF THE PROJECT. JOINT DETERMINATION OF ANY CHANGES SHOULD BE MADE IN AN APPROPRIATE MODIFICATION OF THE ATTACHMENT.

F. Duties of the University

The primary obligation of the University is to exercise its best efforts to achieve the desired results of the project within the estimated costs. The University will appoint a Principal Investigator, subject to approval from the Sponsor. The duties of the Principal Investigator will be to direct the research project. The Principal Investigator will insure that periodic reports on the progress of the project are transmitted to the Sponsor. These reports shall include research results, projections of future research objectives, prior notice of publications concerning the research, and an accounting of disbursements of project moneys.

The University will provide the Sponsor with prompt notice of its intention to pursue patent protection for research results. The University will undertake application and prosecution of patents with the necessary cooperation and aid from the Sponsor. In the event the University does not wish to pursue patent protection, the Sponsor may do so at its expense and with University cooperation.

The University cannot insure either that any patentable items will result from the project or that, if such discoveries do occur, they will yield income.

COMMENTS--

THE DETAILS OF SECTION VI WILL DEPEND MAINLY UPON THE SPECIFIC POLICIES OF THE UNIVERSITY. THAT THE UNIVERSITY HAVE EXCLUSIVE CONTROL OVER THE MANAGEMENT OF THE PROJECTS IS AN IMPORTANT CONSIDERATION TO AID THE UNIVERSITY IN SAFEGUARDING THE PUBLIC GOOD. IT MAY BE DESIRABLE TO HAVE SOME MANAGEMENT INPUT FROM THE SPONSOR, ESPECIALLY IF THE SPONSOR HAS BEEN ENGAGED IN RELATED RESEARCH OR IF IT OWNS PATENTS OR OTHER INTELLECTUAL PROPERTY CONCERNING THE PARTICULAR FIELD OF RESEARCH. IT MAY PROVE BENEFICIAL TO INCLUDE A STATEMENT THAT THE UNIVERSITY IS ACTING AS AN INDEPENDENT CONTRACTOR, AND NOT AS AN AGENT, JOINT VENTURER, OR PARTNER OF THE SPONSOR. HOWEVER, IN CERTAIN SITUATIONS UNIVERSITY POLICY MAY BE AMENABLE TO JOINT VENTURES OR PARTNERSHIPS IN ORDER FOR THE SPONSOR TO TAKE ADVANTAGE OF CERTAIN INCOME TAX PROVISIONS SUCH AS THE CAPITAL GAINS TAX.

THE UNIVERSITY MAY CHOOSE TO STATE THAT IT MAKES NO WARRANTIES REGARDING THE OUTCOME OF THE RESEARCH. RESPONSIBILITY FOR ANY PRODUCTS OF THE RESEARCH IS TO REMAIN THE SPONSOR'S, PARTICULARLY REGARDING SAFETY, MARKETABILITY, EFFECTIVENESS, ETC.
REASONABLE PRECAUTIONS TO PROTECT THE SPONSOR'S TRADE SECRETS SHOULD BE DELINEATED, OR SAFEGUARDS MIGHT BE LIMITED TO DISCLOSURE OF POSSIBLE CONFLICTS OF INTEREST, THE SIGNING OF OATHS OF CONFIDENTIALITY, AND ADEQUATE RECORD-KEEPING.

GENERALLY THE UNIVERSITY RETAINS OWNERSHIP OF PATENTS FOR THE RESULTS OF ITS RESEARCH. IT WOULD BE QUITE BENEFICIAL IN MANY CASES TO HAVE THE SPONSOR PAY FOR PATENT APPLICATIONS. A LIMITED EXCLUSIVE LICENSE COULD BE GIVEN TO THE SPONSOR IN EXCHANGE FOR FINANCING OF PATENT APPLICATIONS. IN SUCH CASES THE UNIVERSITY WOULD RETAIN THE RIGHT TO TAKE OVER THE LICENSE WHERE THE SPONSOR FAILED PROPERLY TO EXPLOIT PATENTS. THE MAJOR UNIVERSITY OBJECTIVE IN THE ADVANCEMENT OF KNOWLEDGE WOULD STILL BE UPHELD, AND THE UNIVERSITY THEN WOULD BE ABLE TO SAVE THE MONEY THAT WOULD NORMALLY BE SPENT ON THE RISING COSTS OF PATENT APPLICATIONS. THIS OBJECTIVE HAS BEEN MET IN MANY UNIVERSITY/INDUSTRY COOPERATIVE RESEARCH EFFORTS.

THE UNIVERSITY MAY WISH TO RETAIN THE RIGHT TO REPLACE THE PRINCIPAL INVESTIGATOR. IN SUCH CASES SPONSOR APPROVAL IS GENERALLY REQUIRED. A SEPARATE SECTION OUTLINING THE SPECIFIC DUTIES OF THE PRINCIPAL INVESTIGATOR IS OFTEN INCLUDED IN UNIVERSITY/INDUSTRY CONTRACTS.

6. Duties of the Sponsor

The Sponsor shall provide all funding for this research project in advance of actual disbursement by the University for research. Funding will be provided according to the attached schedule which has been developed by the parties to this agreement. The Sponsor will provide to the Principal Investigator and the University any knowledge or intellectual property rights which relate to the subject of this research project which are in its possession prior to the inception of this agreement and which it may acquire thereafter. This will include adequate rights to patents in order to allow the University to use the Sponsor's preexistent expertise in conducting the research.

COMMENTS--

ESPECIALLY IMPORTANT IN SECTION VII IS THAT FUNDS WILL BE PROVIDED TO THE UNIVERSITY IN ADVANCE. GENERALLY, A UNIVERSITY IS UNABLE TO ADVANCE MONEY FOR SUCH A PROJECT. IT WOULD ALSO BE USEFUL TO INCLUDE SPECIFICALLY FOR WHAT THE MONEYS WILL BE SPENT, E.G., ONLY FOR WAGES, SUPPLIES, AND EQUIPMENT, OR INCLUDING OVERHEAD SUCH AS MAINTENANCE AND UTILITIES. ALSO, "PROMPT NOTICE" SHOULD BE SPECIFIC, E.G., WITHIN TWO MONTHS.

SOME UNIVERSITY/INDUSTRY AGREEMENTS HAVE PROVIDED FOR OWNERSHIP OF PATENTS TO BE HELD BY THE SPONSOR. IN SUCH CASES, THE SPONSOR SHOULD BE REQUIRED TO PROVIDE THE UNIVERSITY WITH PROMPT NOTICE OF ITS DESIRES TO PURSUE PATENT PROTECTION FOR RESEARCH RESULTS. THE UNIVERSITY SHOULD THEN PROVIDE COOPERATION AND AID AND BE ENTITLED TO PURSUE PATENTS WHERE THE SPONSOR DOES NOT WISH TO DO SO.

H. Publication, Copyrights, and Trade Secrets

Publication and dissemination of information are integral to the purpose of the University. Therefore, the University shall be the sole judge of what it will publish and shall have the exclusive right to publish any and all results of this research project, subject only to such rights of the Sponsor to protect trade secrets. There shall be no publicity or disclosure of information about the project without prior notice to the Sponsor. If the decision is made to publish the results of project research, patent rights shall be preserved with respect to research discussed in publications. A copy of any papers or presentations shall be submitted to the Sponsor for any comments or suggestions before publication. The University shall have the exclusive right to all copyrights which result from the research project.

All publications shall give proper credit to appropriate parties to this agreement.

While free dissemination of information strongly underlies the purpose of the University, certain information and documentation must remain confidential for the protection of the Sponsor. Any trade secrets which the Sponsor has disclosed for the purposes of this project shall be kept in strict confidence, absent the express, written consent of the Sponsor. All confidential information shall be conspicuously marked, and all who work on the project shall agree to protect all confidential information. Information that is developed during the scope of this project shall not be required to be kept confidential beyond the time necessary to perfect patent rights, except to the extent that it involves the sponsor's basic interest in trade secrets.

> COMMENTS--
>
> IT MAY ALSO BE DESIRABLE OR USEFUL TO INCLUDE LIMITATION PERIODS IN SECTION VIII WHICH STATE HOW LONG CONFIDENTIAL INFORMATION MUST REMAIN SECRET. PROVISIONS MIGHT ALSO BE ADDED FOR CERTAIN INFORMATION THAT EMANATES FROM THE PROJECT TO BE KEPT SECRET AT THE REQUEST OF THE SPONSOR. PROVISIONS MIGHT BE INCLUDED TO REFLECT UNIVERSITY AND SPONSOR POLICIES REGARDING THE USE OF THEIR NAMES IN PUBLICATIONS. UNIVERSITIES GENERALLY PROHIBIT THE USE OF THEIR NAMES IN COMMERCIAL ADVERTISING. IT IS IMPORTANT TO EXAMINE CONSTITUTIONAL AND LEGISLATIVE PROVISIONS IN CONNECTION WITH THE DOCTRINE OF PUBLIC PURPOSE IN RELATION TO THIS CLAUSE.
>
> IN CASES WHERE THE SPONSOR RETAINS OWNERSHIP RIGHTS IN PATENTS, SPECIFIC TIME PERIODS SHOULD BE INCLUDED FOR THE DELAY OF PUBLICATIONS TO ALLOW TIME TO SUBMIT PATENT APPLICATIONS. A 60-DAY PERIOD WOULD BE REASONABLE FOR BOTH PARTIES.

I. Press Releases

Statements concerning the research project conducted under this agreement shall not be made or released to any medium of public communication by the Sponsor, except with the prior, written consent of the University, or by the

University, except with the prior, written consent of the Sponsor. Exception is made hereunder to the regular reports of the University, which may include the name of the Principal Investigator, the title of the project, the name of the Sponsor, and the amount of funding provided.

> COMMENTS--
>
> THIS SECTION IS INCLUDED IN ORDER TO PROTECT THE SPONSOR FROM PREMATURE DISCLOSURE OF VITAL INFORMATION AFFECTING PATENT RIGHTS AND OTHER PROTECTION OF INTELLECTUAL PROPERTY.

J. Patent Rights

The University shall maintain title to all patents which are derived from this research project. The Sponsor shall receive a right of first refusal to a license in such patents in return for a reasonable royalty based on the gross receipts from products manufactured under such patents. The Sponsor is obliged to exercise all reasonable diligence to create and promote a public and commercial demand for products which are developed under license granted by this agreement. In the event the Sponsor does not fulfill its obligation to exploit patent rights, such patent rights shall revert to the University to be used in accordance with its policies. In any event, the right to use the patents for scientific pursuit and education shall remain in the University. All rights of researchers to any patents shall be governed by the internal policy of the University.

> COMMENTS--
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> THE PATENT SECTION OF THE CONTRACT IS AN IMPORTANT CONSIDERATION FOR THE SPONSOR, BECAUSE PATENTS PROVIDE DIRECT ACCESS TO PROFITS.
>
> THE SECTION OF THE CONTRACT CONCERNING PATENT RIGHTS WILL VARY SIGNIFICANTLY DEPENDING ON THE POLICIES OF THE UNIVERSITY AND THE SPONSOR. TRADITIONALLY LICENSE TERMS WOULD BE NEGOTIATED ONLY AFTER BOTH PARTIES KNOW EXACTLY WHAT IS BEING LICENSED. HOWEVER, SUCH TERMS MAY BE INCLUDED IN THE ACTUAL CONTRACT AS AN INDUCEMENT FOR PRIVATE SPONSORS TO ENGAGE IN COLLABORATIVE RESEARCH EFFORTS WITH THE UNIVERSITY. GENERALLY, THE UNIVERSITY WILL WISH TO RETAIN TITLE TO THE PATENT. SINCE IT IS IMPORTANT TO THE UNIVERSITY'S FUNCTION TO MAINTAIN MAXIMUM UTILIZATION AND AVAILABILITY OF THE PATENT TO THE PUBLIC, A CLAUSE SHOULD BE INSERTED THAT REQUIRES THE SPONSOR TO EXERCISE DUE DILIGENCE IN EXPLOITING AND MARKETING THE PATENT. THE UNIVERSITY MAY WISH TO OBTAIN SOME DEGREE OF CONTROL OVER LICENSING AND SUBLICENSING BY THE SPONSOR IN ORDER TO PROTECT THE PUBLIC PURPOSE OF THE UNIVERSITY.
>
> MANY UNIVERSITY/INDUSTRY AGREEMENTS GRANT GENEROUS PATENT RIGHTS TO THE SPONSOR IN ORDER TO RECEIVE SUBSTANTIAL FUNDING. OFTEN THE SPONSOR IS GRANTED "ALL SUBSTANTIAL RIGHTS" IN PROJECT PATENTS. THIS IS QUITE USEFUL IN THE UTILIZATION OF CAPITAL GAINS TAX PROVISIONS.

THE UNIVERSITY MAY BE REQUIRED BY POLICY TO RETAIN ALL SUBSTANTIAL RIGHTS IN THE PATENTS AND ISSUE EXCLUSIVE AND/OR NON-EXCLUSIVE LICENSES TO THE SPONSOR. ALSO, THE INCOME THAT THE UNIVERSITY RECEIVES FROM THE USE OF THE LICENSE MAY TAKE ON VARIOUS FORMS, SUCH AS, A PERCENTAGE OF THE SELLING PRICE, A FIXED COMMISSION, A PERCENTAGE OF NET SALES, A SET ASSIGNMENT FEE, ETC.

THE CONTRACT MIGHT CALL FOR A DISTRIBUTION OF PATENT RIGHTS BETWEEN THE SPONSOR AND THE UNIVERSITY. IN THAT CASE, EACH PARTY WOULD RECEIVE AN UNDIVIDED INTEREST IN ALL SUBSTANTIAL RIGHTS TO THE PATENT. THERE ARE DIFFICULTIES IN UTILIZING UNDIVIDED INTERESTS, DUE TO UNCERTAINTY IN REGARD TO TAX STATUS WITH INTERNAL REVENUE RULES AND REGULATIONS. CAREFUL ATTENTION SHOULD BE DIRECTED TO THE APPROPRIATE PROVISIONS OF SECTIONS 1221, 1231, and 1235 OF THE INTERNAL REVENUE CODE WHEN EMPLOYING CONTRACT TERMS WHICH PLACE ALL SUBSTANTIAL RIGHTS IN PATENTS INTO UNDIVIDED INTERESTS.

THE UNIVERSITY SHOULD BE CAREFUL NOT TO GRANT PATENT RIGHTS TO INVENTIONS THAT HAVE BEEN DEVELOPED IN PART OR IN WHOLE BY FUNDS OUTSIDE OF THE AGREEMENT. ONE REASONABLE SAFEGUARD IS TO ALLOW THE GRANTING OF RIGHTS ONLY TO PATENTS WHICH BOTH HAVE BEEN CONCEIVED AND REDUCED TO PRACTICE UNDER THE SCOPE OF THE AGREEMENT.

K. Project Assets

All assets which are acquired with funds distributed under this agreement shall remain the property of the University.

COMMENTS--

THIS SECTION IS INCLUDED BOTH FOR THE BENEFIT OF THE UNIVERSITY IN OBTAINING CERTAIN PROPERTY AND FOR THE PROTECTION OF THE SPONSOR'S RIGHT TO TAX DEDUCTIONS FOR RESEARCH AND EXPERIMENTATION.

L. Mutual Cooperation and Modification of the Agreement

Both parties agree to assist and cooperate with each other, especially regarding their respective rights to publication and patent rights. The parties shall meet at the end of each year to discuss the continued feasibility of the project and any modifications in funding or scope that may be necessary or desirable. Any and all modifications shall be in writing and signed by both parties.

COMMENTS--

THIS SECTION IS INCLUDED TO EMPHASIZE THE DIVERGENT INTERESTS OF THE PARTIES AND THE NECESSITY TO WORK CLOSELY TOGETHER IN NEGOTIATIONS. ALSO, MANY PROJECTS WILL CHANGE COMPLEXION OVER THE TERM OF THE CONTRACT, AND

ADJUSTMENTS MAY BE NECESSARY EITHER WITH RESPECT TO FUNDING OR SCOPE OF THE RESEARCH.

M. Termination Rights

In the event the Sponsor is not satisfied with the progress of the research project, the Sponsor may terminate the agreement upon reasonable notice. The University may terminate the agreement upon proper notice if conditions beyond its control preclude continuation of the project. If termination occurs, the Principal Investigator shall direct the conclusion of the project, issue a final report, and return all unexpended funds. The disposition of equipment and research material involved with or generated by the research project shall be decided by mutual assent to the extent not specified herein.

COMMENTS--

THIS SECTION IS EXTREMELY USEFUL IN THE BARGAINING PROCESS. DEPENDING UPON THE SIGNIFICANCE AND MAGNITUDE OF RIGHTS OR BENEFITS GIVEN TO THE SPONSOR AND UPON THE LIKELIHOOD OF SUCCESS OF THE PROJECT, THE SPONSOR OR THE UNIVERSITY MAY WISH TO GRANT OR RECEIVE TERMINATION RIGHTS. TERMINATION ON THE PART OF THE SPONSOR SHOULD ALWAYS BE SUBJECT TO A MINIMUM PAYMENT PROVISION, SO THE SPONSOR WILL NOT BE ENRICHED UNJUSTLY BY INFORMATION THAT HAS BEEN PROVIDED AND TO PROTECT ANY SALARIES AND LONG TERM COMMITMENTS THAT ARE BEING PAID WITH PROJECT FUNDS. THE UNIVERSITY MAY DESIRE THE RIGHT TO TERMINATE IF IT APPEARS THERE WILL BE LITTLE BENEFIT TO THE UNIVERSITY PROGRAMS OR TO THE PUBLIC. THE RIGHTS TO TERMINATE MIGHT BE VERY NARROW OR VERY BROAD, I.E., THERE MAY BE MANY CONDITIONS PRECEDENT OR ONLY FEW, DEPENDING UPON THE CIRCUMSTANCES OF THE AGREEMENT.

N. Arbitration

In the event of the inability to resolve a dispute between the Sponsor and the University concerning the terms or conditions of the agreement, said dispute shall be settled by arbitration before a single arbitrator in accordance with the prevailing rules of the American Arbitration Society, and judgement upon the award rendered by the arbitrator may be entered in any court having jurisdiction. The arbitrator shall be appointed by mutual consent.

COMMENTS--

AN ARBITRATION CLAUSE SHOULD BE INCLUDED IN ORDER TO AVERT LENGTHY AND COSTLY DISPUTES. THE ARBITRATION CLAUSE MAY BE MODIFIED IF THE PARTIES SO DESIRE. ONE SUGGESTED CHANGE WOULD BE TO USE THREE ARBITRATORS INSTEAD OF ONE. EACH ADVERSE PARTY WOULD APPOINT ONE ARBITRATOR; THE ARBITRATORS SO APPOINTED WOULD THEN APPOINT A THIRD IMPARTIAL ARBITRATOR BY MUTUAL CONSENT.

BINDING ARBITRATION MAY BE IMPOSSIBLE FOR MANY STATE UNIVERSITIES DUE TO EITHER CONSTITUTIONAL OR STATUTORY RESTRAINTS. IN THE EVENT OF DISPUTES, THE CONTRACT MAY REQUIRE TERMINATION IF A REASONABLE SOLUTION CANNOT BE FOUND.

THE SITE OF THE ARBITRATION PROCEEDINGS SHOULD BE SPECIFIED AS THE STATE IN WHICH THE UNIVERSITY IS LOCATED. THE UNIVERSITY SHOULD NOT BE REQUIRED TO INCUR THE EXPENSES OF HIRING OUT-OF-STATE COUNSEL AND TRAVELING TO AN OUT-OF-STATE LOCATION.

O. Exclusivity of Funding

All funding for this project shall be provided by the Sponsor.

COMMENTS--

UNIVERSITY POLICY MAY PROHIBIT AN EXCLUSIVE FUNDING PROVISION. FURTHERMORE, THE UNIVERSITY MAY NOT WISH TO LIMIT ITSELF TO THE SPONSOR'S FINANCING. THE NEED AND/OR OPPORTUNITY MAY ARISE FOR ADDITIONAL FUNDING OF WHICH THE UNIVERSITY WOULD WISH TO AVAIL ITSELF. HOWEVER, THE SPONSOR MAY BE HESITANT TO PROVIDE FUNDS WHICH WILL BE COMBINED WITH OTHERS, SINCE THE SOURCE OF EXPENDED FUNDS MAY NOT BE DETAILED SUFFICIENTLY FOR PURPOSES OF TAX DEDUCTIONS AND RIGHTS TO RESULTING DISCOVERIES.

THE UNIVERSITY WILL OFTEN PAY THE SALARY OF THE PRINCIPAL INVESTIGATOR AND/OR OTHER RESEARCHERS, IN WHICH CASE THIS SECTION SHOULD BE ADAPTED ACCORDINGLY.

P. Assignment

Either party may assign its rights, remedies, obligations, or liabilities arising under this agreement provided prior, express, and written consent is obtained from the other party. The assignee must assume all responsibilities under the agreement and agree to be bound thereby.

COMMENTS--

THE UNIVERSITY SHOULD RECEIVE PRIOR APPROVAL OF ASSIGNMENT TO PROTECT ITS PUBLIC PURPOSE RESPONSIBILITY. THE UNIVERSITY SHOULD BE ASSURED THAT THE ASSIGNEE WILL CONTINUE TO PROVIDE SUPPORT AND ASPIRE TO THE GOALS OF THE ORIGINAL SPONSOR. THE SPONSOR, ON THE OTHER HAND, MUST BE SURE THAT THE WORK CAN BE CONTINUED ADEQUATELY BY AN ASSIGNEE.

Q.
Insurance and Liability

The University shall be responsible for maintaining all facilities that are used for performing work on the research project. The University shall maintain adequate workers' compensation insurance for its employees working on the research project. The Sponsor shall maintain adequate products liability and third party liability insurance in respect to the project. The Sponsor shall indemnify the University against the claims of third parties in regard to the specific utilization of any marketed research results.

COMMENTS--

THIS SECTION IS IMPORTANT TO DEFINE MORE COMPLETELY THE RESPONSIBILITIES OF THE PARTIES AND PROTECT THEIR RESPECTIVE INTERESTS. BY MAINTAINING PROPER INSURANCE TO COVER RESEARCH FACILITIES AND WORKERS, THE UNIVERSITY IS DEMONSTRATING ITS EXCLUSIVE RESPONSIBILITY FOR MANAGEMENT OF THE RESEARCH PROJECT. THE SPONSOR'S MAINTENANCE OF ADEQUATE PRODUCTS LIABILITY AND THIRD PARTY LIABILITY PROTECTION IS IMPORTANT IN UPHOLDING THE UNIVERSITY'S PUBLIC PURPOSE RESPONSIBILITIES.

WHERE THE UNIVERSITY IS A SELF-INSURER AND WILL NOT MAINTAIN OUTSIDE INSURANCE, IT SHOULD BE REQUIRED TO INDEMNIFY THE SPONSOR AGAINST WORKERS' COMPENSATION CLAIMS WITHIN THE SCOPE OF THE PROJECT. WHERE THERE IS INSURANCE, INDEMNITY SHOULD BE LIMITED TO THE AMOUNT OF INSURANCE COVERAGE.

IT IS RECOGNIZED THAT RESEARCH ACTIVITY, PRODUCT DEVELOPMENT, AND PRODUCT USE MAY ALL GIVE RISE TO LOSSES OR COSTS FROM UNEXPECTED OUTCOMES. SOME LOSSES MAY BE IMMEDIATELY OBVIOUS, AND OTHERS MAY ONLY BECOME APPARENT YEARS LATER. THE QUESTION OF WHETHER THE PARTIES TO A RESEARCH AGREEMENT, THE USER OF THE PRODUCT, OR SOCIETY GENERALLY SHOULD BEAR THE COSTS IS UNDER STUDY BY THE COMMITTEE. THE RESEARCH CONTRACT CAN BE USED TO ASCERTAIN THE INTENT OF THE PARTIES WITH REFERENCE TO THE ALLOCATION OF FINANCIAL RESPONSIBILITY AND LIABILITY.

R. Notices

All notices and communications pertaining to this agreement shall be in writing. They shall be delivered personally or sent by first class mail to the following:

a) to the Sponsor-- ______________________________
____
____
____

b) to the University-- ______________________________
____
____
____

COMMENTS--

BOTH THE PERSON(S) AND PLACE(S) FOR NOTICE SHOULD BE SPECIFIED. FOR THE SPONSOR IT MAY BE THE PRESIDENT OR OTHER EXECUTIVE OF THE COMPANY AT ITS PRINCIPAL OFFICE.

THE UNIVERSITY MAY REQUIRE THAT NOTICE BE DELIVERED TO THE PRINCIPAL INVESTIGATOR, THE PRESIDENT, OR PERHAPS THE DEAN FOR RESEARCH. TIME PERIODS IN WHICH NOTICE MUST BE RECEIVED SHOULD BE INCLUDED AS WELL AS WHEN SUCH PERIODS SHOULD BEGIN AND END, E.G., UPON RECEIPT, UPON DELIVERY, UPON MAILING, ETC.

S. Integration, Severability, Headings, and Contract Terms

This agreement and attached appendices and exhibits constitute the entire agreement between ________________________________ (the University) and ________________________________ (the Sponsor) with respect to the research project entitled, ____. All modifications shall be in writing and signed by both parties.

All agreements and covenants contained herein are severable, except those establishing the research project and those regarding protection of confidential information, publication rights, and patent rights. If any agreements or covenants, apart from the named exceptions, are held invalid by a court of appropriate jurisdiction, this agreement shall be interpreted as if such agreements or covenants were not included.

The headings in this agreement are intended only for convenience of reference and shall be given no legal effect in construction or interpretation.

The waiver by either party hereto of any right hereunder or failure to perform or breach by the other party shall not be deemed as a waiver of any other right hereunder or of any other breach or failure by said other party whether of a similar nature or otherwise. The failure of either party to enforce at any time the provisions of this agreement, or any rights in respect thereto, or to exercise any election herein provided, shall in no way affect the validity of this agreement. The exercise by either party of any of its rights herein or any of its elections under the terms or covenants herein shall not preclude or prejudice either party from exercising the same or any other right it may have under this agreement, irrespective of any previous action or proceeding taken by either party hereunder.

COMMENTS--

AN INTEGRATION CLAUSE IS INCLUDED TO INSURE THAT EXTRANEOUS OR UNOFFICIAL DOCUMENTS OR AGREEMENTS ARE NOT INTRODUCED TO IMPLY ADDED CONDITIONS TO THE AGREEMENT. IT IS UNDERSTOOD THAT THE ENTIRE AGREEMENT IS EMBODIED IN ONE DOCUMENT UNLESS ADDITIONS OR MODIFICATIONS OCCUR LATER BY PRESCRIBED METHOD. IT IS ALSO DESIRABLE TO MEET THE LEGAL REQUIREMENTS FOR SEVERABILITY. IN THE EVENT THAT INDIVIDUAL SECTIONS OF THE AGREEMENT ARE FOUND INVALID BY AN APPROPRIATE COURT, THOSE SECTIONS MAY BE DELETED FROM THE AGREEMENT WITH THE REMAINING PARTS LEFT INTACT.

T. Governing Laws

This agreement shall be governed by and construed in accordance with the laws of ______________________________.

> COMMENTS--
>
> THE GOVERNING LAWS SECTION IS INCLUDED MERELY TO PRECLUDE ANY JURISDICTIONAL PROBLEMS OR CHALLENGES SHOULD THE AGREEMENT BECOME SUBJECT TO CONTROVERSY OR LITIGATION. LOCAL STATUTES AND LIMITING FACTORS IN RELATION TO GOVERNING LAWS SHOULD BE CONSULTED.
>
> GENERALLY THE LAWS OF THE STATE IN WHICH THE UNIVERSITY IS LOCATED SHOULD CONTROL. IT IS NOT REASONABLE TO EXPECT THE UNIVERSITY TO HIRE OUT-OF-STATE COUNSEL IN THE EVENT OF A DISPUTE IN COURT.

U. Definitions

"All substantial rights" to a patent means all rights of value at the time the patent is transferred, which are generally the rights to make, use, and sell the patented subject matter. An undivided interest in all substantial rights is an equal percentage of each and every substantial right. All substantial rights does not include patent rights that are restricted to particular industries or territories unless the patent is useful only in those industries or territories.

"Best efforts" means with diligence that reasonably is due an important research project.

"Intellectual property rights" include all patents and applications for patents or certificates of plant variety protection as well as trade secrets, copyrights, and trademarks.

A "license" of a patent is the grant of anything less than all substantial rights. It conveys a covenant by the patent owner not to sue for the manufacture, use, or sale of that which is covered by the patent.

"Memorandum of agreement" or "agreement" means this agreement between ____________________________________ (the University) and ______________________________________ (the Sponsor) dated ___________________ for the project entitled, ____, and all attached appendices and exhibits.

"Patent rights" shall include all patents issued under Title 35 of the United States Code, all foreign patents, as well as Certificates of Plant Variety Protection issued under Title 7, Sections 2321 et seq. of the United States Code.

"Principal Investigator" is the project leader and coordinator who is designated by the University with the approval of the Sponsor. All management of the project is directed by the Principal Investigator.

"Project assets" are all articles of tangible property which are purchased with project funds for use by the researchers in performance of the project.

"Project funds" are all moneys advanced to the University by the Sponsor for use in the project.

"Researchers" are all University employees including the Principal Investigator, who have been assigned to work on the project and who have signed a research agreement.

"Research project" or "the Project" is the work entitled, __________ ______________________________, and is the subject of this agreement.

"Trade Secrets" are any formulae, patterns, devices, or compilations of information which are used in the Sponsor's business, provide the Sponsor a competitive advantage, and are marked "trade secret" and "confidential."

V. Research Agreement

In consideration of my selection to participate in the research project entitled, ______________________________, and funded by ____________________ (the Sponsor), and of payments due under the agreement, I hereby agree:

1. to abide by all terms of the agreement;
2. to communicate all research results promptly and fully;
3. to keep accurate, witnessed, daily records of the research;
4. to assist the University and the Sponsor in any way to pursue patent rights;
5. to maintain in strict confidence all trade secrets that are disclosed by the Sponsor for use in this project;
6. to reveal any conflicts of interest or potential conflicts of interest, which I may have, due to either private consulting arrangements or other associations which may be related in subject matter to the attached agreement;
7. to disclose all patents or certificates of plant variety protection that have been issued in my name or that I have assigned to another which relate to the project;
8. to seek no outside funds from either a public or private Sponsor for the work to be performed pursuant to this agreement; and
9. that all rights to inventions and project assets in connection with this research project belong to the University as described in the agreement.

COMMENTS--

THE RESEARCH AGREEMENT MAY OR MAY NOT BE ATTACHED. IT SHOULD BE SIGNED BY EACH RESEARCHER, OR SEPARATE AGREEMENTS SHOULD BE SIGNED BY EACH RESEARCHER. THE PURPOSE OF THE RESEARCH AGREEMENT IS TO APPRISE EACH PARTICIPANT IN THE PROJECT OF THE FACTS SURROUNDING THE ARRANGEMENT. EACH RESEARCHER SHOULD BE AWARE OF THE UNIQUE ISSUES INVOLVED IN THIS UNIVERSITY/INDUSTRY COOPERATIVE EFFORT. BY VIRTUE OF SIGNING A RESEARCH

AGREEMENT, THE RESEARCHERS WILL BE BOUND TO THE TERMS OF THE AGREEMENT BETWEEN THE SPONSOR AND THE UNIVERSITY. THIS IS ESPECIALLY IMPORTANT CONCERNING THE TREATMENT OF INTELLECTUAL PROPERTY.

DUE REGARD SHOULD BE PAID TO THE RELATIONSHIPS AMONG GRADUATE STUDENTS, PROFESSORS, THE UNIVERSITY, AND THE SPONSOR IN THE FORMULATION OF CONTRACTUAL OBLIGATIONS.

THE RESEARCHERS MIGHT RECEIVE DIRECT PAYMENTS FROM THE SPONSOR IF UNIVERSITY POLICY DOES NOT PROHIBIT IT. OTHERWISE ALL PAYMENTS SHALL BE MADE THROUGH APPROPRIATE UNIVERSITY CHANNELS.

IN CONNECTION WITH RECOMBINANT DNA RESEARCH, IT IS INCUMBENT THAT THE RESEARCHERS STRICTLY ADHERE TO THE GUIDELINES PROMULGATED BY THE NATIONAL INSTITUTES OF HEALTH (VOL. 48 FEDERAL REGISTER, P. 24556, JUNE 1, 1983).

ADEQUATE PRECAUTIONS MIGHT BE ADDED TO THE RESEARCH AGREEMENT TO PROTECT ALL FORMS OF INFORMATION WHICH ARE DERIVED FROM THIS PROJECT. THE NEED FOR SUCH PROTECTION MIGHT ARISE WHEN A RESEARCHER LEAVES THE EMPLOY OF THE CONTRACTING INSTITUTION FOR A NEW POSITION. AN APPROPRIATE SAFEGUARD WOULD BE TO PROHIBIT ANY USE OUTSIDE THE PROJECT OF ANY INFORMATION DERIVED FROM THE PROJECT DURING ITS TERM AND FOR A SPECIFIC TIME PERIOD FOLLOWING ITS CONCLUSION.

W. Funding Arrangements

$______ shall be paid to the University on the date the project is to begin. $______ shall be paid on the first of each month thereafter, beginning ________________ until the date the project is scheduled to be completed.

COMMENTS--

THE FUNDING ARRANGEMENTS MAY TAKE MANY FORMS. MONTHLY PAYMENTS MAY NOT BE PRACTICAL, SO PROVISION FOR QUARTERLY OR SEMI-ANNUAL PAYMENTS MIGHT BE MADE. PAYMENTS MIGHT BE MADE AS NEEDS ARISE OR AS DETERMINED WHILE THE RESEARCH PROGRESSES. FUNDING SHOULD BE RECEIVED BY THE UNIVERSITY IN ADVANCE IN ORDER TO INSURE THE PROPER CONTINUATION OF THE RESEARCH. IN ALL CASES, THE FUNDING SCHEDULE SHOULD BE DEFINITE AND SPECIFIC.

THE AGREEMENT MIGHT INCLUDE PROVISIONS FOR BONUS PAYMENTS FOR INTERIM ACCOMPLISHMENTS OF THE RESEARCHERS. SUCH ARRANGEMENTS SHOULD BE SET FORTH IN SPECIFIC AND DEFINITE TERMS.

IV. Advantages of Close Working Relationships with Industry

The dissemination of useful information from research is a complex process. In agriculture, the extension of information has been institutionalized in part through the Cooperative Extension Service involving local, state and federal funding and leadership. Policies relating to consulting and other forms of informal information dissemination reflect the presence and the mission of the extension function carried out on a partnership basis with the Land-Grant University as the primary source of new and regenerative information for agriculture and related enterprises.

Institutions have generally recognized that individuals involved in research may carry on private information disseminating activities within the limits of established policies. Such policies generally assume that a full measure of intellectual effort is rendered to the University in accordance with the contractual commitment of the individual to the University. Moreover, the policies generally assume, at least implicitly, that the University has some interest in consulting and information dissemination activity undertaken on the grounds that such efforts not be incompatible with the general University mission of providing credible, objective information to individuals, firms and other users.

Quite clearly, the University mission is best served by highly motivated, adequately compensated individuals functioning at the frontiers of knowledge. Close working relationships with private firms, government agencies and nonprofit organizations functioning in the public interest can further those objectives. In that regard, it should be assumed that the advice and counsel of the most able faculty members will be sought by those outside the University. Within established limits, consulting and other forms of information dissemination including lecturing and preparation of books, films and audio and video materials are compatible with the mission of the University. Consulting on the part of faculty can be viewed within the public interest for the following reasons:

A. The transfer of information is accelerated and there is an earlier realization of the benefits from research.

B. The faculty member gains insights into real world problems and the adequacy of available information in solving such problems.

C. Through such private information dissemination activities involving the preparation of legislation, the resulting institutional framework is more likely to be complete, useful, and in accord with the state of knowledge at that time.

D. Through service as an expert witness and as a consultant on matters in litigation, court decisions are more likely to reflect the insights gained through research.

V. Problem Areas Merting Attention

If a faculty member engages in information dissemination on a private basis, conflicts may arise. Those conflicts may relate to perceptions that outside interests receiving consultation on a private basis are being favored unduly, perceptions that the faculty member faces a conflict of interest in allocation of intellectual effort and perceptions that consulting arrangements, especially those engaged in intensively over a lengthy period, may lead to non-objectivity on the part of the faculty member.

A. Conflicts Related to Favoring Outside Interests

A college or University faculty or staff member engaged in non-university sponsored work may encounter actual or apparent conflicts of interest in several different settings. Conflicts may arise from--

-- Consulting and other assistance rendered to a funding firm or agency by a researcher who is heavily dependent upon that particular source of research support and with a deep interest in continuation of that support.

-- Undertaking research on a private basis to serve the research or informational needs of a private firm without disclosure of such undertaking to the University and to the sponsoring agency.

-- Purchase of major items of equipment and supplies for University research from a private firm in which a faculty or staff member has an interest without disclosure of the interest.

-- Transmission to the private firm (or other user for private gain) of University-sponsored discoveries or information which may not be generally available for private use.

-- Participation in the negotiation (or influence upon the negotiation process) of contracts or other relationships relating to the faculty or staff member's privately-sponsored research involving a private firm or firms with which the faculty or staff member has consulting or other significant relationships.

-- Acceptance of payments of items of significant value from private firms with which the University does or may have research or commercial relationships, under circumstances which might reasonably be interpreted as an attempt to influence the recipients in making decisions or in conducting their affairs.

-- Making payments to employees of non-university agencies with which the University does or may have research or commercial relationships under circumstances which might be viewed as an attempt to influence decison making.

-- Engaging in part-time employment on a regular basis with a non-university employer as a means of channeling research results on a regular and systematic basis to favored users.

-- Engaging in private information dissemination utilizing the benefits of public investment (without administrative review to assure that the public interest is adequately protected).

-- Utilizing equipment or graduate research assistants (or other public funded personnel) to develop information specifically for private information dissemination efforts, and utilizing equipment or graduate assistants funded through non-public sources (other than the beneficiary of the private information dissemination effort) without disclosure to the agency funding the equipment and graduate assistants.

B. Conflicts of Interest Relating to Allocation of Effort

Every faculty and staff member faces competing demands upon time and energy from teaching, research, extension, committee work, other University and community service, management of investments, outside consulting and, in some instances, practice of a profession. Allocations of time and energy among the various competing demands do not raise ethical questions or questions of conflict of interest unless the University or private individuals or firms involved are misled in the understanding of the amount of effort actually devoted to particular activities.

C. Conflicts in Consulting on an Intensive and Long-Term Basis

If a University faculty member or employee intensively engages in private consulting in the same technical field as the individual's research projects over a lengthy period, questions may be raised as to whether that advice and consultation are provided in a manner and in a setting that assure continuing objectivity. If in undertaking and carrying out consulting or other arrangements involving the giving of advice or dissemination of information full disclosure is made to the University and to the private firm insofar as the activities would appear to relate to work for the University or work for the private firm, conflicts are less likely to arise. A long-term and intensive consulting relationship is tantamount to part-time employment by the firm.

D. Effects of Differing Limitations

If limitations on consulting and other forms of private information dissemination differ by college or function within the University, problems may arise relating to morale and the perception of inequity in treatment by the University as employer. Moreover, differences in rules governing such activity may be translated into disadvantageous treatment with respect to promotion, tenure and merit-related salary adjustments. In evaluating differences in limitations on private information dissemination efforts, however, consideration should be given to the expectations of funding agencies and the land-grant philosophy and mission of service.

VI. Human Capital-The "Brain Drain"

During the late 1970's and early 1980's there was fear on the part of academicions, and others that intensification of biotechnological research efforts in the private sector would create a demand for human capital with the consequence of dislocating scientists from Universities to the private sector in a disproportionate number. There has been movement of scientists from Universities to industry, especially well established individuals at the advanced Associate Professor and Professor levels. However, the worst fears have not been realized and information derived from a survey of the State Agricultural Experiment Stations in 1983 indicated that the movement of scientists from University (State Agricultural Experiment Stations) to industry was about the same as the movement of scientists from one University to another. This still remains a critical concern and it has been aggravated by the fact that many States either have or are attempting to develop biotechnological research environments attractive to industry. One of the principle themes for improving a states' environment for biotechnological industrial development has been to create centers or institutes for biotechnology and to attempt to staff these centers with highly qualified senior scientists. In addition, Universities have been more active in recent years in the establishment of Emminent Scholars Chairs and similar kinds of appointments where outstanding senior faculty are desired. Demands on the part of the latter two activities cannot be met by existing resources and there will be a tendency to hire less qualified individuals to simply fill existing positions. This type of expansion will introduce an additional degree of instability in research and education programs of the Land-Grant Universities.

VII. Regulation of Biotechnological Research and Development

Efforts to regulate biotechnological research and development activities are in progress at both the national and state levels. Depending upon the structure and nature of the regulatory processes that are finally adopted, there could be serious negative impacts on the development of University/Industry relationships. For example, unreasonable demands for environmental impact assessments pertaining to field experimentation and/or commercial releases could be so costly that they might deter industry from further investment in such an effort or they might prevent the University from pursuing such an activity. Land-Grant Institutions and the scientific community in general are concerned about the potential impacts of the products of biotechnological research and development and would support a reasonable program of regulation. The Division of Agriculture Committee on Biotechnology of the National Association of State Universities and Land-Grant Colleges has prepared a proposal for the "regulation" of biotechnological research and development in the area of food and agriculture. A copy of this proposal has been provided to the Subcommittee for inclusion in the record.

VIII. Summary

A variety of mechanisms exist whereby Universities and industries may interact in research and development that are mutually beneficial to both parties. Numerous examples exist of successful University/Industry cooperative efforts. If future potential cooperative activities are discussed or negotiated in an open environment where full disclosure of each parties interests and related efforts is made, then workable arrangements can be developed without violating the principles and goals of the cooperating institutions and industries. Sensitivity to the basic issues outlined in this presentation is essential to the development of an effective cooperative relationship.

Mr. Brown. Thank you very much, Mr. Sauer. Dr. Knutson?

Mr. Knutson. I am Ron Knutson. I am the professor of agricultural policy at Texas A&M University.

I want to briefly summarize my testimony and request that the full statement be included in the record.

Mr. Brown. Without objection, so ordered.

Mr. Knutson. Public institutions are created under a specific social contract that instills certain obligations by which their performance is judged. The agricultural research and extension system was created under a unique social contract. It specified that technology discovered in the system was to be freely available to all individuals and/or firms desiring to exploit it. As a result of this social contract, land-grant scientists have historically worked with firms and/or individuals in developing, adopting, and implementing new technologies without protecting private property rights.

That social contract now appears to be unraveling. The source of the change is a series of congressional actions and court decisions that have extended patent rights to plant varieties, living organisms, and computer software.

Policy decisions regarding patent rights have opened the door for the patenting of potentially all new products of the bio and information technology era. OTA found in 1983 that there were 61 companies pursuing applications of biotechnology in animal agriculture and 52 companies applying biotechnology to plants. Most of these firms have developed their own in-house research capability employing molecular biologists, biochemists, geneticists, plant breeders, and veterinarians.

Relationships are also developing between many of these firms and universities. At Stanford University, five corporate sponsors contributed $2.5 million to form the for-profit Engenics and the not-for-profit Center for Biotechnology Research.

Michigan State University, a land-grant, created Neogen to seek venture capital for limited partnerships to develop and market innovations arising out of the university's research.

The establishment of bio and information technology property rights has substantially heightened scientists' interest in private sector employment opportunities. In the process, questions have arisen over who maintains the property rights, the university, the private firm, or the scientist.

It does not take much imagination to recognize the potential profound implications of such developments on the land-grant university system. It is now possible to patent virtually all discoveries within the system. With little apparent regard for its social contract implications, a variety of arrangements between land-grant universities, scientists and private firms have been spawned. These arrangements are designed to protect and capture the profits from the system's discoveries. While previously treating government-business ties at arm's length, such private sector arrangements integrate business into the university fabric. Questions develop over who controls the university research agenda, the allegiance of scientists to their university employer, the willingness of scientists to discuss research discoveries having a potentially patentable product associated with them, and the political favoritism shown particular companies by universities because of their research ties.

The advent of patent rights, exclusive licensing, and private sector investment in public sector research has the potential for changing the distribution of benefits from the land-grant research discoveries. These changes warrant direct public discussion and consideration by policy makers. They occur for at least five reasons.

First, by exclusive licensing or transfer of patent rights to private firms, the right to use discoveries is no longer freely available, even if the information on the discovery itself is freely available.

Second, certain individuals and/or firms are conferred the benefits of specific land-grant research to the potential detriment of others. Prior to the transfer of property rights, of discovery rights, the benefits were available to anyone who adapts a land-grant discovery to commercial usage.

Third, the costs of the resulting discoveries are internalized in the price of the resulting product. The price the public pays for the product also includes any monopoly rents associated with the conferral of the rights. Society pays twice: Once for the cost of the research and then again for its benefits. Without the conferral of property rights, rents are minimized by competition.

Fourth, private sector—public sector inequities are virtually assured in any granting of research property rights to an individual firm. This occurs because with the relatively small private sector investment there is access to a much broader range of current and prior research.

Fifth, the existence of patent rights, trade secrets and confidential information has many potentially adverse implications for extension in terms of an increased burden for product testing, the potential lags in information, and the absence of research information that would previously have been readily available.

To the credit of the system's experiment station committee on policy, these questions have been and are being addressed. However, the basic social contract issue has not been resolved. The right to use discoveries is no longer freely available.

While it is easy to suggest that these apparently unforeseen effects of conferring property rights could be contrary to the public interest, it has to be recognized that the issues involved have complex competitive elements associated with them. Property rights increase the willingness of private sector firms to invest in and develop discoveries in the marketable products. If the land-grant system refuses to confer property rights on its discoveries, it is not in a position to compete for the support of its research program by private industry.

The system's ability to compete for the services of top scientists is therefore adversely affected. With limited resources, the system has been placed in a position where it could not win if it refused to participate in the newly conferred rights. That does not negate the profound implications for the nature of the system. The conference of property rights of the system discoveries has had some interesting but predictable effects on the allocation of resources within the agricultural research complex.

Striving to capture the competitive share of private property funding, land-grant resources are shifting more in the direction of basic bio and information technology research. As resources are diverted to address more basic research issues, there is a potential gap developing in the traditional system function of problem solving and new product testing.

It can be argued that increased private sector involvement in the research function should make the system more responsive to problem solving research. That may be the case for problems of national scope and significance. However, many agricultural problems are local or regional in scope. The applied nature of the system having an agricultural experiment station and Extension Service in each State has provided the unique capacity to identify and solve local or regional problems. Reality suggests that only certain universities have sufficient resources to compete for private sector support in the bio and information technology era.

A dichotomy of have and have-not universities is created. In the process, traditional extension research interaction and feedback mechanisms could thereby break down, particularly in States that are not in a position to command a major biotech component. This could become a major problem in New England, in the South, in the Great Plains, and in the Northwest.

One of the traditional roles of the system has been to test new inputs used in agricultural production as they become available to the public. Testing new production inputs has traditionally been a function of the experiment station scientists. Extension Service scientists take the results of that research to farmers. Costs associated with individual farmers testing inputs and making errors in their use is thereby materially reduced. Testing and evaluation of new agricultural input is becoming a less popular research activity.

In some instances these functions are being forfeited by the experiment station and pushed over to the Extension Service. Interestingly, the Extension Service has no research charter, an item of contention in the California research neutrality litigation.

The product testing function becomes more important in the biotech era than it has been in the past because a flood of new complex production inputs is expected to enter the market.

In times of rapid technological changes, there are often suggestions to attempt to stop or even turn back the hands of time. Applied to bio and information technologies, such a strategy would be counterproductive and unwise. U.S. agriculture has been very successful because of technological advance, yet consideration of specific changes in research and extension policy may be justified.

The following implications merit consideration.

First, the social contract upon which the agricultural research and extension system was created needs to be reevaluated. This issue should not be left for resolution by the courts. And I fear that that is what is happening as illustrated by the California litigation. Specific guidelines need to be developed which, while allowing the system to compete, protects the public interest and their investment in agricultural research and extension function. Both the Congress and the USDA should have an interest in this type of policy development.

And I saw very little interest expressed earlier by the USDA, I might add.

It is sometimes suggested that increased private sector support for agricultural research signals less need for public support. While private sector support is complimentary to public support, basic bio and information technology research is very costly. A reduced role for public research and extension would provide a lower level of protection for public health and welfare. In addition, there is strong public interest in maintaining an agricultural research component in each State to serve the problem solving needs of its agriculture.

The role of extension is even more important than it has been in the past. And I find it very curious that the USDA, for example, had no one from extension up here at the table.

New, more complex products require evaluation and explanation. In States where experiment stations have attracted substantial private sector support, the product testing function can be most objectively performed by extension.

And I might add that even here there is a question. Where, if university scientists have discovered a new product, can scientists in other branches of the university objectively evaluate for farmers the contribution of that new product, if private sector property rights exist or are vested in that university, and they stand to benefit from it?

As a result, explicit authority should be provided for extension to have the flexibility to engage in highly applied research function such as product testing and evaluation. A system of matching Federal funds might be provided for that purpose. In other words, what I am suggesting is that, in addition to a high priority research function, you might consider a high priority extension function as well for the purpose of product testing work.

The OTA study of technology, public policy, and the changing structure of agriculture concludes that evolving bio and information technology will be biased in favor of large-scale farms. That conflicts with earlier testimony, obviously.

Unless special attention is given to technology generation and transfer to moderate size farms, major structural changes could result, leading to the eventual demise of family farm organizations. To the extent that preservation of family farms is a policy objective, special funding for and emphasis upon the problems of technology generation and transfer to moderate size farms is warranted.

Next, while the agricultural research system has received the benefits of increased funding from both private and public sources, extension funding has not materially increased. As a result, extension staff at the county and specialist level are becoming caught up in a whirlwind of technological change. The result is a need for the injection of substantial staff development funding into the extension system.

The point is that a basic structural reevaluation of the organization of the extension function of the agricultural research and extension system is needed. Such a reevaluation will inevitably need to tackle the politically sensitive issues of the role of county, State, and Federal components of the Extension Service. Thank you.

[The prepared statement of Dr. Knutson follows:]

PREPARED STATEMENT OF DR. RONALD D. KNUTSON

Much of the success of American agriculture is attributable to the creation of its agricultural research and extension system. For well over a century, the public has seen fit to invest substantial sums of money in the agricultural research and extension system at federal and state levels. The resulting technology has been a driving force in maintaining the competitive position of U.S. agriculture in world markets. Bio and information technologies represent a new era in agricultural research. This new era results from the potential impact upon the rate of technological change; the challenges presented for the organizational structure of research and extension; and the potential impact upon the structure of agriculture.

Agriculture has already entered into the era of bio and information technologies (OTA, Aug. 1984). Manifestations include growth regulators, embryo transplants, computerized farm management decision models, and electronic auction markets. While there is nothing new about technological change in agriculture, both the rate and complexity of change appear to be accelerating. The driving forces behind this acceleration include:

- Sharply accelerated public sector investment in basic biotechnology research beginning in the early 1970s (OTA, January 1984).
- Even sharper increases in private sector investments associated with the conference of private property patent rights in living organisms and computer related technology (software).

These changes have the most fundamental implications for the Land-Grant University System since its creation. In addition, U.S. agriculture could be dramatically restructured as a result of fundamental changes in the technology discovery and transfer environment.

The System's Social Contract

Institutions are created under a specific social contract that instills certain obligations by which their performance is judged (Locke et al.). The agriculture research and extension system (hereinafter referred to as the System) was created under a unique social contract. It specified that technology discovered in the System was to be freely available to all firms and/or individuals desiring to exploit it. As a result of this social contract, Land-Grant scientists have historically worked with firms and/or individuals in developing, adopting, and implementing new technologies without protecting property rights.

That social contract now appears to be unraveling. The source of change is a series of Congressional actions and court decisions that have extended patent rights to plant varieties, living organisms, and computer software (OTA, Jan. 1984).

Policy changes regarding property rights in agricultural research had their origin in the enactment of the Plant Variety Protection Act of 1970. Of possibly greater significance was the 1980 landmark U.S. Supreme Court decision, *Diamond vs. Chakrabarty,* which held that the inventor of a new micro-organism, whose invention otherwise met the legal requirements for obtaining a patent, could not be denied a patent solely because it was alive. *This decision opened the door for patenting of potentially all new products of the biotechnology era.*

Since the passage of the Plant Variety Protection Act and the *Chakrabarty* decision, private sector interest in agricultural research has mushroomed. OTA, for example, found that in 1983, there were 61 companies pursuing applications of biotechnology in animal agriculture and 52 companies applying biotechnology to plants. Most of these firms have developed their own in-house research capability employing molecular biologists, biochemists, geneticists, plant breeders, and veterinarians.

Relationships are also developing between many of these firms and universities. For example, Monsanto has a 5 year $23.5 million contract with Washington University under which individual research projects are conducted. At Stanford University, five corporate sponsors contributed $2.5 million to form the for-profit Engenics and the not-for-profit Center for Biotechnology Research.

Such relationships are not limited to private universities. Michigan State University (a Land-Grant) created Neogen to seek venture capital for limited partnerships to develop and market innovations arising out of the University's research. The formation of Neogen points up a significant problem being encountered by the universities in the biotechnology era. Neogen was formed, in part, for the purpose of retaining faculty members who are getting employment offers from biotechnology companies. In Neogen, faculty members are allowed to develop their entrepreneurial talent and obtain the associated financial rewards, while remaining at the university.

The formation of Neogen reflects the reality that biotechnology development is resulting in or has the potential to result in a substantial drain on university basic and applied research talent. If leading faculty members are not overtly hired away from universities, they may form their own companies or become consultants. The establishment of biotechnology property rights has substantially heightened scientists' interest in private sector employment opportunities. In the process, questions have arisen over who maintains the property rights--the university, the private firm, or the scientist.

In the Washington University - Monsanto case, the University retains the patent rights while Monsanto has exclusive licensing rights. In Engenics, Stanford likewise gets the patent rights while Engenics receives the royalty-bearing licenses. Neogen buys the patent rights from Michigan State University while the inventor gets a 15 percent royalty or a stock option in Neogen.

It does not take much imagination to recognize the potentially profound implications of such developments on the Land-Grant university system. It is now possible to patent virtually all discoveries within the System. With little apparent regard for its social contract implications, a variety of arrangements between Land Grant universities, scientists, and private firms have been spawned. These arrangements are designed to protect and capture the rents from System discoveries. While previously treating government-business ties at arms-length, such private sector arrangements integrate business into the university fabric. Questions develop over who controls the university research agenda, the allegiance of scientists to their university employer, the willingness of scientists to discuss research discoveries having a potentially patentable product associated with them, and potential favoritism shown particular companies by the university because of their research ties.

The current magnitude of private sector commitment to agricultural research is largely unknown. Studies suggest that it may approach $3 billion (National Agricultural Research and Extension User's Advisory Board, p. 59). Approximately half of this is spent on production agriculture and half on food production or post-harvest technology research. Private sector research resources are obviously devoted to those areas having the highest short-run profit potential. Also, despite recent large increases in private sector agricultural research, questions remain as to the long term willingness of private sector firms to invest large sums of money in agricultural research and the breadth of such research. There has been a distinct tendency for private firms to cut back on research first in times of adversity.

To the credit of the System's Experiment Station Committee on Policy, these questions have been and are being addressed. However, the basic social contract issue has not been resolved. The right to use discoveries of the System is no longer freely available. Certain individuals and/or firms are being conferred exclusive benefits to the possible detriment of others. The effect is to internalize the costs and/or rents from discoveries of the predominantly publicly supported system. With internalization, the potential for inequities or patronage creeps into the system with plausibly profound impacts on the structure of agriculture.

While it is easy to suggest that these apparently unforeseen effects could be contrary to the public interest, it has to be recognized that the issues involved have complex competitive elements associated with them. Property rights increase the willingness of private sector firms to invest in and develop new discoveries into marketable products (Evenson). If the Land-Grant system refuses to confer private property rights on its discoveries, it is not in a position to compete for the support of its research program by private industry. The System's ability to compete for the services of top scientists is thereby adversely affected. With limited resources the System has been placed in a position where it could not win if it refused to participate in the newly conferred rights. That does not negate the profound implications for the nature of the System.

Changing Research-Extension Roles

The conferrence of property rights of System discoveries has had some interesting, but predictable, effects on the allocation of resources within the agricultural research complex. Striving to capture a competitive share of private sector funding, Land-Grant resources are shifting in the direction of more basic bio and information technology research. As resources are diverted to address more basic research issues, there is a potential for gaps developing in the traditional System functions of problem solving and new product testing.

It can be argued that increased private sector involvement in the research function should make the System more responsive to problem solving research. That may be the case for problems of national scope and significance. However, many agricultural problems are local or regional in scope. The applied nature of the System, having an Agricultural Experiment Station and Extension Service in each state, has provided a unique capacity to identify and solve local or regional problems. Reality suggests that only certain universities have sufficient resources to compete for private sector support in the bio and information technology era. A dicotomy of "have and have not" universities is created. In the process, traditional extension-research interaction and feedback mechanisms could thereby breakdown--particularly in states that are not in a position to command a major biotech component. This could become a major problem in New England, the South, the Great Plains, and the Northwest.

One of the traditional roles of the System has been to test new products as they become available to the public. Product testing has traditionally been a function of Experiment Station scientists. Extension Service scientists then take the results of that research to farmers. The costs associated with individual farmers testing products and making errors in their use is thereby materially reduced.

New product testing and evaluation are becoming a less popular research activity. In some instances, these functions are being forfeited or even pushed over to the Extension Service. Interestingly, extension has no research charter--an item of contention in the California research neutrality litigation. The product testing function becomes more important in the biotech era than it has been in the past because a flood of new complex products is expected to enter the market.

Implications

In times of rapid technological change there are often suggestions to attempt to stop or even turn back the hands of time. Applied to the bio and information technology era, such a strategy would be counterproductive and unwise. U.S. agriculture has been very successful because of technological advance. Yet consideration of specific changes in research and extension policy may be justified. The following implications merit consideration:

- The social contract upon which the agricultural research and extension system was created needs to be reevaluated. This issue should not be left for resolution by the courts. Specific guidelines need to be developed which, while allowing the System to compete, protect the public interest and investment in the agricultural research and extension functions. Both the Congress and the USDA should have an interest in this type of policy development.
- It is sometimes suggested that increased private sector support for agricultural research signals less need for public support. While private sector support is complementary to public support, basic

bio and information technology research is very costly. In addition, there is a strong public interest in maintaining an agricultural research component in each state to serve the problem solving needs of its agriculture.

- The role of Extension is even more important than it has been in the past. New, more complex products require evaluation and explanation. In states where Experiment Stations have attracted substantial private sector support, the product testing function can most objectively be performed by Extension. As a result, explicit authority should be provided for Extension to have the flexibility to engage in highly applied research functions such as product testing and evaluation. A system of matching Federal funds might be provided for this purpose.
- The OTA study of *Technology, Public Policy, and the Changing Structure of Agriculture* concludes that evolving bio and information technology will be biased in favor of large scale farms. Unless special attention is given to technology generation and transfer to moderate-size farms, major structural changes could result--leading to the eventual demise of family farm agriculture. To the extent that preservation of family farms is a policy objective, special funding for and emphasis upon the problems of technology generation and transfer to moderate size farms is warranted.
- While the agricultural research system has received the benefits of increased funding from both private and public sources, extension funding has not materially increased. As a result extension staff at the county and specialist levels are becoming caught up in a whirlwind of technological change. The result is a need for the

injection of substantial staff development funding into the extension system.

In addition, basic organizational issues need to be addressed by the Extension Service as it enters the bio and information technologies era.

The theory upon which extension was developed was that of the research scientists conveying the knowledge of discoveries to the extension specialist who, in turn, supplies information to the county agent who teaches the farmer. Over time, this concept has gradually but persistently broken down as agricultural technology has become more complex, and insufficient resources have been devoted to staff development. As a result, more emphasis has been placed on direct specialist-to-farmer education. More specialists have been placed in the field to have closer proximity to their clientele, but at the cost of less contact with research scientists.

The point is that a basic structural reevaluation of the organization of the extension function of the agricultural research system is probably needed. Such a reevaluation will inevitably need to tackle politically sensitive issues of the role of the county, state, and federal components of the Extension Service.

Mr. **Brown**. Thank you, Dr. Knutson. Your statement is extremely useful; somewhat provocative. Of course, it opens up to public debate some of the critical issues which I am sure is what you intended to do.

Mr. Volkmer.

Mr. **Volkmer**. Yes, I have several questions.

Mr. Sauer, on the proposed agreement that we have submitted to the committee here, that has been developed, has this been disseminated throughout the land-grant colleges?

Mr. **Sauer**. Yes, it has, in the form of progress reports from our committee. It has been provided to the directors of research, the deans of agriculture, and actually directly to key faculty who are working in the biotechnology area, and to research administrators.

Mr. **Volkmer**. What I find in here is somewhat of a little bit—and I don't know the answer, the complete answer, and Dr. Knutson addressed it. It provides in here that on this there shall be no publicity or disclosure of information about the project without prior notice to the sponsor. And the decision made to publish results of project research, patent rights, shall be preserved with respect to research discussed in publication.

It goes on to provide in here somewhere that information developed during the scope of this project shall not be required to be kept confidential beyond the time necessary to perfect patent rights.

So, what I am seeing in here is, basically, that it is looking to that the sponsor would have the patent rights and that the university can publish but only publish that information that the sponsor basically says is not part of the trade secrets that we have given you to help develop the research to begin with. And, second, he can't publish anything that would impinge on the patent rights until the patent has been perfected, at least filed.

Is that correct?

Mr. **Sauer**. Essentially, yes. What it proposes is that the university would delay publishing long enough to give the sponsor an opportunity to file for a patent. But that does not mean that the sponsor can prevent the university from publishing that information. We feel that any undue delay in sharing that information with the scientific community would be at odds with the general purpose of a public university.

Mr. **Volkmer**. And then we do run into the problems of—let's say, as Dr. Knutson has pointed out, that the research does come with something that is tangible, as far as a result is concerned, for an application somewhere. And the company goes ahead to prepare, formulate it, and distribute it and sell it. Can they use the university's name and part of that by saying that it has helped develop along with the university of so and so?

Mr. **Sauer**. Chairman Brown, Congressman Volkmer, that is a very key question, of course. We have run into problems in the past where the university's name has been used in advertising, indicating that the product was tested at a given university. That does not necessarily imply endorsement of the product. I think that is a separate issue and relates to——

Mr. **Volkmer**. That's——

Mr. SAUER [continuing]. I think the product testing issue that Dr. Knutson was raising.

Mr. VOLKMER. That's what I——

Mr. SAUER. He may want to comment on that.

Mr. KNUTSON. I think quite clearly if the university—if the firm that holds the rights, whether they be patent rights or exclusive marketing rights, if the firm that holds the rights can use the university's name, I think to a farmer out there that implies clearly that the university is suggesting that they use this product. And that is exactly the problem that I was pointing out earlier, if I could use the name of ARCO in vain here maybe, but if I could use the name of ARCO——

Mr. VOLKMER. XYZ.

Mr. KNUTSON [continuing]. Or XYZ Corp., and Texas A&M University, and we developed a product for which XYZ has exclusive patent rights, it's a little bit difficult to see us in our product testing function, turning around and saying to farmers that they ought not use that product. It creates a real conflict of interest and a real test of the objectivity of the system under those circumstances.

Mr. VOLKMER. Well, in certain areas I am sure that especially in Texas and other places, Texas A&M has a very good reputation. And, so, if XYZ in their advertising of the product says this is developed in conjunction with the University of Texas A&M, how are you going to stop that?

Mr. KNUTSON. I think that that is an area that certainly ought to be looked at from a policy standpoint. I think it is highly questionable whether a firm should be allowed to use the university's name.

Mr. VOLKMER. Then the next question you address—and I think it is very legitimate—when you have a product so developed, how does extension or anybody else in the governmental body go ahead and determine the efficacy of it?

Mr. KNUTSON. Boy, I think that's a very, very tough issue. I would only comment that I think that university should probably withdraw in terms of its own evaluation of a product and defer to the test results by other universities in terms of use of that product. That raises questions, however, where you have a product that is regional in scope and its application on a regional basis. We produce more cotton than any other State, as you well know. And the results of a particular discovery may be different in Texas in terms of the application of a particular pesticide to control the boll weevil, for example, than it might be in California.

So, you know, I don't know how you get around those problems. The unfortunate thing, I think, is that there are very few people that are seriously addressing those kinds of issues.

Mr. VOLKMER. I would like to ask Dr. Fox if you have any comment to make in regard to this complete discussion.

Mr. FOX. Well, universities have been profiting on the results of their inventions for many, many years. Certainly that part of it is not new. The Wisconsin Alumni Research Foundation has garnered a considerable amount of money for the benefit of the university as a result of the work in such things as irradiated ergosterol, vitamin D in our milk. And I think, clearly, none of us would disagree that that is in the public interest to do so. Obviously, they license that to private companies who took the results of that invention and somebody made some money, some of which came back to the university. I don't think we should have a problem with that.

Likewise, I don't think we should have a problem with private organizations who want to stimulate areas of research in the university, much as the commodity groups do in agricultural universities who, for example, want to stimulate research in tomatoes and give money for tomato breeding research, so long as the fruits of that research are made freely available to everyone.

I do have a problem, however, as I indicated previously, with the funding of a particular specified contractual research project in any university from a private company, for many of the reasons that we have just heard. It is difficult for me to imagine the ethical problems that a scientist must have when in the morning he works on his USDA or NSF funded research project, and in the afternoon works on what is in many cases perhaps exactly the same project, in this case in a company in which he has some equity participation or is sponsored by a private concern.

So, I think that raises ethical problems of such a nature that our own company has decided not to participate in this sort of affair.

Mr. **Volkmer**. Thank you, Mr. Chairman.

Mr. **Brown**. Mr. Packard?

Mr. **Packard**. Dr. Knutson, in your testimony you concluded that evolving bio and information technology will be biased in favor of the large-scale farmer and has been biased in that direction. In what way has that bias manifested itself, and what can be done to change that so that it gives equal treatment to the family farm and they can benefit on an equal basis?

Mr. **Knutson**. I was the chairman of a group of individuals, two of which were past research administrators, and two of us were scientists in the land-grant system. We looked very closely at where that bias develops. It seems to us it develops in two areas, primarily in the area of adoption. It is not that the discovery itself is biased, but it is the fact that the largest farmers tend to be more progressive. They tend to be more involved with their agricultural experiment station and with the USDA in terms of what is going on on the front burner of technological advance. And they are there to adopt a discovery as soon as it becomes available.

That is a major problem area. It relates more to the extension component than it does to the research component per se.

The second possible area of bias does relate to research itself. It relates to questions like in the mechanized agriculture area, where larger scale farm equipment may inherently be biased toward larger scale farms. Now, fortunately, there isn't all that much public investment in that large-scale equipment.

Now, I would add to that, with respect to biotechnology, many of the discoveries are going to be highly complex. Many of them like embryo transplant, if I can use that as an example in the case of dairy. A large scale farmer, I know from my own research, can profit by employing embryo transplant technology in dairy. A smaller scale farmer could not profit by doing that. And the difference simply lies in the fact that the smaller scale farmer would have to hire a veterinarian, a highly trained veterinarian to do it on a custom basis, while a large-scale farmer can develop his own expertise internally within that farm operation.

I might say that Mr. Brown knows that in the Southwest and in the whole area from Texas over to California and up into the Northwest we do have many farmers, many dairy farmers, many large-scale dairy farmers who are applying embryo transplant technology internally in their own operation. We projected in the OTA study that that could well result in a major regional shift in where milk is produced in the United States: out of the Northeast and upper Midwest, to the Southwest portion of the United States.

Mr. PACKARD. Are there ways in which you have been able to determine what technology could be specifically directed toward the small farmer?

Mr. KNUTSON. Well, I think that that remains an open question. I think in the terms of the area that I have thought the most about, which is this area of embryo transplant in dairy, I think that the big issues in that area relate to the ability of cooperatives to organize themselves to extend that function to typical family farm size operations. Now, whether they can do it as efficiently as the large-scale farms remains to be seen.

As I suggested in my testimony, I do feel that it is worth considering devoting a rather substantial research effort to technology generation for moderate-size farms. I don't profess to have the answers to those questions. My thinking tends to be along the lines that it is more a problem of extension than it is of research.

Mr. PACKARD. Surely I would assume that you and most of the other witnesses would not subscribe to a philosophy that we ought to curtail such research and development, even though it may lead to economic problems for the farmer due to surpluses, or it may discriminate against the small versus the large farmer, et cetera, that the research ought to move forward. And then we ought to look for ways of adapting it to the small, midsized, as well as the larger farmer. I presume that you would subscribe to that?

Mr. KNUTSON. I certainly agree with that philosophy. I think you should move ahead. I think we have to move ahead. If we are going to be competitive in world markets for agricultural products, we have got no choice but to move ahead, when half of our crops go into those world markets.

But at the same time, I think we have got to provide every opportunity for moderate-size farms to survive in this competitive system. I am not at all suggesting that we turn back the hands of time or stop all technological advance.

I think we have got to recognize that we could have substantial displacement in agriculture during the bio and information technology era, however, and we need to overtly deal with that displacement. It may be as great as that occurred with the cotton-picker.

Mr. PACKARD. Or in industry.

Mr. KNUTSON. That's right. Or in industry, exactly.

Mr. PACKARD. Has the way university research, the way it's been done, or the quality of the research done at the university level been affected by the relationships—and this question might be addressed to Mr. Sauer. Have the relationships with industry and the university affected the quality of research being done in either the industry level or the university level?

Mr. **Sauer**. I can judge that most directly only from my own experience at the University of Minnesota. I feel overall that the quality of our research, the appropriateness, the timeliness of it has improved through some of these relationships with industry. It has, frankly, made some of our scientists more aware of what is happening in the real world and the kind of cutting-edge research we need to do to keep that technology frontier moving forward.

Mr. **Packard**. Has there been, in your judgment, an adequate flow of information between industry and the university level as a result of information coming from technological research?

Mr. **Sauer**. I am not sure that it is ever fully adequate. That is a constant challenge for us. I think some of the kinds of comments I made earlier about a potential agreement or contract could perhaps improve that flow of information.

I would like to follow on that and emphasize a point partly in response to earlier questions as well as yours. My goal as an administrator of public agricultural research program at a major university is to serve the public good. Sometimes the public good is best served by not entering into any exclusive agreements, not any licenses, but by freely turning over the results of the research to the public, and for any company that wants to take that product and develop it and market it. Public plant varieties might be an example.

But we are entering an era where we are talking about very costly research in biotechnology. In some cases it might be in the best interest to serve the public good by entering into an exclusive contract, so we have the resources to do the research and development and that there is a company that indeed has the incentive to take the product and further develop it and market it. And without that exclusive agreement, that new technology could well sit on the bookshelf of the scientist.

So, I think the bottom line is, what is the best way to serve the public good.

Mr. **Packard**. Well now, if there is a fairly adequate and a cooperative exchange of information between industry and the university, is there concentrated efforts being made to pull industry's funding capabilities into either the development and marketing of the research or even into extension of the research itself, and, perhaps even more important, the application of it to the farmer or to the user of the research and the technology?

Mr. **Sauer**. Again, I can speak largely for my own experience. I think our interest is adding to our resources to support research, to continue to serve the public good. I don't see what you suggested happening, at least at our institution.

In terms of our total research program, right now 4 percent of our budget comes from the private sector. I don't think that is a percentage sufficient to talk about a substantial redirection, motivation apart from the overriding support from the public sector. But I think it does speak to the importance of keeping strong public support for our research programs.

Mr. **Packard**. What percentage, if you were to give just an estimate—and maybe you have some figures; I wouldn't expect them—

what percentage of industry in the biotechnical areas of agriculture are benefiting from the research done at the university level?

Mr. **Sauer**. I don't think I could give a good answer to that. If Dr. Wood were here, he probably could, but I——

Mr. **Packard**. Far more than 4 percent, I would assume.

Mr. **Sauer**. Yes, that's right.

Mr. **Packard**. In other words, industry is benefiting from the research that is being done at the university level, financially benefiting, and at this point in time are not contributing back to the process on an equitable basis, in your judgment?

Mr. **Sauer**. I think that is true in individual situations. I have been concerned that, when we enter into such agreements, that the resources coming into the university as a part of that agreement are sufficient to really offset the cost of the research and, hopefully, in addition add to our resources to continue to serve the public good. And that has not been the case in the past in many situations.

Mr. **Packard**. It would appear to me that universities could do a better job of soliciting and actually working with industry to try to pull additional funding in, far more than 4 percent.

One last question if you would permit, Mr. Chairman. In all of the testimony we have heard today there has been just an underlying theme that seems to keep coming back to me and particularly as it relates to the small- and mid-sized farmers. And the question has to come to the point, how do we get the small farmer or the farmer that is struggling economically just to keep afloat, how do we get them to spend the time to be educated, to spend the money to implement much of the research that would make it more productive for them and, frankly, put them in more competitive position? How do you get farmers to do what they already know how to do, better than they do?

Mr. **Sauer**. I guess I'll make a comment, because nobody else wants to.

Obviously, education plays a role, a very important one, and extension does, and Dr. Knutson could say that. But I think some things are simply a scale of size, a scale of size dictated by other kinds of policies in this country: economic policies, tax laws, and incentives, and even international policies over which we have relatively little control, that have caused the growth we have seen in terms of large farms, corporate farms, and so on. So, I think you are dealing with an area that is beyond the kind of research we have been talking about today.

I don't think it's outside the realm of the research program that I am responsible for. And I have been concerned that we would redirect more of our current resources to research on agricultural and food policy and perhaps be able to provide you and your colleagues with better recommendations as to what could be done if you chose to move in that direction of protecting, if you will, family farms, providing better incentives, tax relief, whatever it might be. The bottom-line question is, to what extent is the public willing to subsidize smaller farms to keep them competitive, if indeed a subsidy is part of what is necessary.

Mr. **Knutson**. I think the answer to your question is a very complex one. I think that it is clear that we don't know nearly as much about the social side of agriculture as we know about the technical side of agriculture. We haven't invested that much in knowing why it is that, when you have an extension meeting, the large farmers show up, and they, maybe, don't benefit as much as the middle-size farmers who aren't there; or they don't benefit as much as the middle-size farmers would have if they had been there. And why it is that that happens, I really don't know. I just have a difficult time figuring it out.

We did a major study of the economies of size associated with different farms in the High Plains of Texas. We had a hundred farms in the study, and they ranged in size all the way from down around 150 acres to over 4,000 acres. We looked at all types of economies of size, both in terms of whether they are able to produce at a lower cost, assuming the same input cost, the fact that large farmers can buy inputs at lower price, and the fact that large farmers are able to sell their products at a higher price. And we asked the question when we were all done—and, incidentally, the study showed substantial economies of scale, all the way up through 4,000 acres in size. And we asked the question when we were all done as to why it was that the large farmer was more successful.

We concluded that it was, more than anything else, the fact that he spends less time, less percentage of his time, a smaller percentage of his time, on the seat of the tractor and more time operating the farm as a businessman. Now, maybe he could do that by virtue of the scale of his operation alone, but it goes back to the point that as an extension economist I frequently see in my meetings: relatively few moderate-size farms and a preponderance of large or very large farmers in those meetings. It is an interesting phenomenon. Why it occurs, I don't know.

Mr. **Packard**. I had occasion to visit with my sister and her family who are—and her husband, who are farming up in Idaho, quite a ways away from my district. But I happened to see them this past weekend. As most farmers, small farmers in this country, they are struggling just to continue to farm. That is all they know. The problem is, of course, it's a whole complex problem of how to stay afloat, but knowing what to plant, what the market is going to bear. And they live in an area where the options of planting a variety of crops are available to them. But they lose consistently simply because they are not advised or not educated as to what would the world market bear.

Often, the small farmer does not follow the world market situations, the world climatic situations, the trends in crop marketing, to the point where they can adjust or they can alter their course to better meet that world market. A bigger farmer perhaps has got tools and abilities to do that better than the small farmer, or maybe they just do it better.

It would appear to me that maybe in a part of the Extension Service there could be information made available as to what market conditions are throughout the world, what wheat is doing, and what dairy is doing, and what hay is doing, and what sugar beets are doing, and maybe assist at least in the decisionmaking as to whether to plant this crop or that crop.

I don't know. What is your observation?

Mr. **Knutson**. I think that goes on already.

Mr. PACKARD. It does——

Mr. KNUTSON. The question is, how do you get those moderate-size farmers to use the information that is available?

Mr. PACKARD. That is, I guess, the question.

Thank you, Mr. Chairman.

Mr. BROWN. Dr. Sauer, I know you have to leave. But before you leave, I wanted to comment that I think you and/or Dr. Wood have made a substantial contribution in the presentation of the contract outline structure which you made here and its application in this emerging field of plant biotechnology.

I would just like to inquire as to the extent to which you have reviewed and borrowed from, to the extent that it is applicable, the prior work that has been done in the areas of human biotechnology and other related areas. I am reminded of the struggle that went on at Harvard when they entered into that cooperative agreement with the German firm. And I am sure there are many other examples where they have tried to work out some of these very delicate political and economic policy questions.

Have you tried to build on that prior background and take advantage of it?

Mr. SAUER. Chairman Brown, yes, we have, very directly. We have not tried to reinvent the wheel. We have tried to benefit from some of those concerns in the States. And I think when you look at our complete reports, you will see many of those concerns and ideas represented in the report.

I would also like the record to show that Dr. Wood chaired this committee. While I served on it along with several other of my peers from across the country, he has really provided the leadership for the intensive study that we have undertaken and have not yet completed. If it weren't for a health problem, he would be here today.

Mr. BROWN. Well, I think that that really should be extremely helpful in the problem of moving plant biotechnology into some degree of parity with developments that have occurred in the other fields of biotechnology.

If you do have to leave, you may excuse yourself.

Mr. SAUER. Thank you very much. I do have to catch a flight back to Minnesota. I do appreciate your consideration and the opportunity to share some ideas with you. Thank you.

Mr. BROWN. It has certainly been a privilege to have you here.

Mr. VOLKMER. Mr. Chairman, could I ask—I know he has a plane, but could you give me one quick answer to a question I would like to ask you since you are head of the instrumentation, university level, biotechnology research. Adequate or inadequate?

Mr. SAUER. That's a severe problem for us, both replacing the equipment and instrumentation that we have and keeping it modern and state of the art. In fact, I will be arguing to our State legislature tomorrow that part of the investment they ought to make in the agricultural experiment station is support for a recurring instrumentation fund so we can build some of that into our ongoing budget support.

I would also share with you one example of a creative approach we have taken to help, not directly related to biotechnology, but perhaps it's applicable in a different way. We have secured funding from our State legislature to build a new dairy barn on our campus for research and teaching. The challenge you always face with a facility like that is how do you keep it modern.

We are entering into an agreement with Lavell, a major manufacturer of dairy equipment, where they are going to provide original equipment for us at 60 percent of cost and then replace it free, as modern equipment replaces that equipment.

Mr. **Volkmer**. Thank you very much.

Mr. **Sauer**. Thank you.

Mr. **Brown**. Let me put you on the spot a little bit, Dr. Knutson. It seems, just trying to project the general thrust of the testimony that we have heard here, that Dr. Sauer is presenting a posture of where the land-grant universities are seeking to move rapidly into this biotechnology area to set up models or patterns of association with private industry and, in effect, try and replicate the progress that has been made in the field of human biotechnology, which resulted from the investment that we made in human capital to the NIH, and so forth.

Dr. Fox has presented the posture of private industry dissatisfied with the progress being made to the land-grant colleges and the institutional mechanisms to date and, in effect, sort of divorcing themselves from it and moving ahead on a basis to capture what he perceives and the industry perceives are markets here.

You, on the other hand, are throwing up cautionary signals and warning that we may be endangering institutional mechanisms that have been of great value to this country in the past and principles with regard to the relationships between Government, universities, and industries which have been tried and proven in the past.

Now, the general thrust of the testimony is that the land-grant system hasn't been doing all that great when it comes to adapting swiftly to large new opportunities and that we need to move more swiftly. Are you, in effect, being an anchor on progress here?

Mr. **Knutson**. I hope not. I am raising some serious questions that I think need to be faced. I think that if they aren't faced specifically by policymakers, they are going at some time to end up in the courts. I think that these are questions that can logically be decided by policymakers as to which way we should go.

I think, for example, the issue of whether extension should have authority to do highly applied research in light of the issue of the potential bias of experiment station scientists doing that research that already has a contract with a private firm is a policy issue. And I could easily see the California courts, not trying to prejudge them, I could easily see them saying that extension has no authority to do research. Well, then the question is that, since California is clearly one of the centers of biotechnology research—some would argue the center of biotechnology research in the United States—then who is going to do it.

Many of the crops, as you well know, that are produced in California are almost unique to California. So, there are some very thorny issues in that kind of an area. I certainly hope that I am not an anchor on progress. I am a very strong believer in the land-grant university system. You have got to recognize at the same time that I am a very strong believer in the family farm system.

I think that one of the obligations of our system of government is to give everybody an equal opportunity. I think we should do everything we can to encourage progress while giving everybody an equal opportunity to survive.

Mr. BROWN. Well, I would like to comment that your remarks with regard to the function of extension are extremely timely. We have been looking at this in the Agriculture Committee with the thought of modifying the extension role to the degree we saw the need for it and rewriting the farm bill, which comes up this year. Our thrust has been on improving this capability of extension to do a more effective job in the dissemination of these new technological developments through improved utilization of the information technologies that are available and which come from another sector, not necessarily from the agricultural sector.

The idea of a research role and a more explicit role in what you call testing and evaluation has not been a predominant point in the testimonies that we have had. I don't think the department has been aggressive in seeking this, and you may criticize them for that, I don't know.

Mr. KNUTSON. I am aware, however, from a work in OTA that they, too, feel that there is a gap developing in what they call the highly applied research area. I think that that is quite logical in light of the scientific rewards associated with more basic agricultural research.

Mr. BROWN. Well, this is not a new problem exactly. We have a long history in the chemical—or as it relates to the chemical industry in agriculture and the need for research and testing. And we have set certain patterns there be existing law which do not give extension a particularly significant role.

It is also not a particularly satisfactory system, from my standpoint.

Mr. KNUTSON. Well, I think, you know, when you are dealing with a firm that is an important constituent in the State and may be an important firm in lobbying on behalf of our budget within a State, for the State to turn around and say that its products are not of the very highest quality and to rank another firm's products above that, who maybe has little economic interest in that State, is itself a challenge. So, I think there are some very important economic and political forces, if you will, that operate in that whole area. And that is why I think it is quite important that we do everything we can to insulate the system. We aren't going to provide complete insulation, but to insulate the system and to provide encouragement for the system to operate with a relatively neutral hand.

Mr. BROWN. You made some comments also about this movement of—perhaps it was Dr. Sauer who made this—about the movement of some scientists to industry. Apparently, he had made certain studies that indicated this was not as serious a problem as might have been indicated, in that there was a similar movement to other universities. Of course, he neglected to mention that there is also a movement from industry to industry, that it is the movement of scientists from, we'll say, Bell Labs or some other large institution to some small entrepreneurial activity that has spawned much of the progress in the electronics and computer field. That is not necessarily an unhealthy situation. There have been several generations of that movement, for example. The latest one that I observed was Wosniak moving from Apple Computer to start another firm because he was dissatisfied with the bureaucratic rigidity of Apple Computer, which is already 5 or 6 years old, I think.

You have experienced these problems, have you, Dr. Fox?

Mr. Fox. We haven't had scientists move from my industry to another industry. But I think the biotechnology industry is so brand new that we haven't seen very much of that happening yet. I am sure we will, as it matures.

Mr. **Brown**. We are still in the first generation of movement.

There is a substantial industry that I am familiar with around the Stanford campus that has resulted from the movement of scientists from the university to their own firms, some of which are quite large now.

Mr. **Volkmer**. Mr. Chairman?

Mr. **Brown**. Yes?

Mr. **Volkmer**. I would say we just had that with the previous panel. We had Mr. Caulder, who moved from Monsanto——

Mr. **Brown**. Yes——

Mr. **Volkmer** [continuing]. To set up his own firm.

Mr. **Brown**. That's right.

People from Missouri do that.

Mr. **Volkmer**. Not as well as California.

Mr. **Brown**. Well——

Mr. **Knutson**. Let me say this, if I could, in reaction to that whole area. My intuitive reaction as an economist is to say, well, that's good because to have that kind of movement reflects the kinds of rewards that exist in the market system and puts a higher price on talent, which is going to attract more people into the area.

My fear, however, is that, unless the universities have sufficient resources to pay substantially higher salaries than they paid in the past to these top scientists, you don't have the top scientists in the universities to train the new scientists that are coming up and that are being employed by Dr. Fox, and so forth.

And I think we need to be very concerned about that type of development.

Mr. **Brown**. You are precisely correct. We have experienced that already in other fields. What we want to do is to foresee these problems to the extent that we can and to provide the proper signals. I don't think we can manage it or plan it, but we can give the proper signals so that the market can adjust, the market for trained manpower, for highly qualified professors, and so on.

We want to know how we can go about giving those signals in the most appropriate way.

Mr. **Knutson**. Well, I certainly think the high priority research special grants program has helped universities to generate the money needed to attract and maintain the very highest quality of scientists. And I think, that is certainly a move in the right direction.

Mr. **Brown**. You also raised a warning signal about this what you referred to as the free availability of land-grant research and development, the patentability of all the products that are coming forth, again a problem resulting from rapid change, from the accumulation of knowledge at a pace that we haven't experienced before.

I am not sure how to go about solving that. I have participated in some of the broadening of the patent legislation, for example, because I thought that there was a larger public purpose to be served here. I want to know when we are treading on dangerous ground when we make it possible to patent life forms, for example, which, incidentally, was done by the courts, not by the Congress. We have in the Congress lagged, as we so frequently do, behind the leading edge of what is happening in this field.

Are you correctly assessing this problem in terms of its impact upon existing institutions and arrangements? Or are you overemphasizing it? I want to ask Dr. Fox the same question.

Mr. KNUTSON. I think I am correctly assessing the problem. I am not saying that the decision to allow patent rights was wrong. I am simply saying that I think at the time we made those decisions—and I might say that the Congress did enact the Plant Variety Protection Act before the court decision——

Mr. BROWN. Before the biotechnology revolution, as a matter of fact.

Mr. KNUTSON [continuing]. And before the court decision, if I remember right on the timing. So, there was some leadership taken there.

What I am saying is that I don't think the profound implications that that would have, have been properly considered. And whether it should have been properly considered by the Congress or whether they should have been properly considered by USDA in terms of the activities of the joint council and the assistant secretary for science and education, I am not sure. But I do think that certainly issues like, if a firm is given a patent right, should it be allowed to use the university's name, in the case of a land-grant, is certainly a very, very viable policy issue that ought to be considered.

So, I am saying, sure, I don't see that the whole patent right issue has been wrongfully pursued. I am simply saying that let's recognize what the implications are, now that it has gone in that direction.

I think we can show through research quite clearly that the amount of private sector interest has increased tremendously since we allowed patent rights. Now the question is, how do we deal with some of the problems that evolve from it.

Mr. BROWN. Dr. Fox, do you want a monopoly on the seed business? Do you want to be able to patent everything that you develop and take all of—what kind of profits do you call them—monopoly profits involved here? Can you be objective in responding to the hazards of the direction we are moving in?

Mr. FOX. I think there are several issues here that I hope we are not confusing. Broadening the patent legislation is an extremely healthy thing to have done for the industry as a whole. That is true both in the university system and for private industry. And I think it stimulated biotechnology enormously.

Dr. Sauer, though, made the key point, I think, a little while ago. That is that the research and testing and FDA approval and such is extremely expensive, and that industry exclusive rights in many cases in order to have an incentive to carry that through. And I don't see any conflict of interest or any problem at all with the university patenting the fruits of its research and then deciding that the best way to get the fruits of that research out to the public is to deal exclusively with one company. That doesn't seem to me to be a problem.

I don't want to confuse that, however, with the other kind of interactions that universities and industries are engaging in, which is to say that industry sponsored a specific kind of research in the university and owns the patent rights. That's a very different kettle of fish, it seems to me. And the question is, why would a university engage in that kind of relationship. And the answer is fairly clear. It is because there is not enough—there are not enough research funds coming from USDA and NSF and such to sponsor the research that they feel necessary to carry out.

Why would industry engage in that kind of an affair? And the reason for that is fairly clear. Industry has not in the past had the foresight to develop its own in-house technical expertise in these areas and now feels itself on the cheap, if you will, to go out and to buy that expertise in universities by supporting research grants.

I submit that there are solutions to those problems which suggest themselves.

Mr. BROWN. I am glad you feel there are solutions to it. But you apparently also feel that—well, it doesn't directly apply to the patent situation, but the engaging in joint research with the universities and the complexity of the problems arising from that, which may include the right to patents and licenses and so on, that that is a sufficiently sticky field that you don't want to get involved in, it seems from your testimony.

Mr. FOX. I agree, that's the way I do feel, which isn't to say, however, that industry ought not to support research in universities. Indeed, I think many industries do. We have a number of no-string grants, no-strings-attached grants. We have given several hundred thousand dollars to the botany department at Berkeley in order to stimulate research there. And they do what they will with that money. I think that's the way industry ought to interact with universities.

Mr. BROWN. Well, we hope that industry will take that point of view, because universities would certainly appreciate it.

I would like to point out that a lot of this activity and modification of the patent laws began before it was clear that it was a factor in biotechnology. There was, as a matter of fact, considerable impetus stemming from the fact that many of our Government laboratories, nonagricultural, were—which fund research to the private sector or universities, were accumulating backlogs of patents which were not being disseminated because of the rigorousness of the legislation or the law with regard to that. So, we started making it easier to get those patents onto the market. And then we began to perceive that, if our basic goal is the widespread commercialization of these patents, then we need to develop a framework within which private industry will be able to recoup more of the benefits, just so that they would be justified in commercializing it. It is expensive to commercialize in many areas.

Do you want to pursue some additional questions?

Mr. **Packard**. I have no further questions, Mr. Chairman.

Mr. **Brown**. Do you have any further questions, Mr. Volkmer?

Mr. **Volkmer**. I know it is probably not appropriate for Dr. Knutson, because you are basically in the area of extension and not in the research area. And it would have been more appropriate for Mr. Sauer, and so I think I—if you don't want to answer it, just don't, and I am going to address it in writing to Mr. Sauer. That is that some of the basic research in the plant, biochemistry and physiology, et cetera, has been testified to by Dr. Fox and Dr. Marvel, it really hasn't been done. And I'd like to know really, can somebody tell me where have our land-grant universities—and I've got one in my State—where have they been the last 20 years? You know, these are basics in plants that we have been producing and stuff in this country for a good many years. I am just curious why that wasn't done.

Can anybody give an answer why it wasn't——

Mr. **Fox**. Well, I have a very highly personal reaction to that. As I indicated before, in my opinion, it is because USDA saw its priorities differently than NIH did. The USDA approach tended to be much shorter term. The funds weren't made available for the kinds of basic research in plant molecular biology that were in animal molecular biology. My own work—and I don't want to be personal about this, but my own work is an example of that. I spent nearly 20 years in a university system working on plant hormone molecular biology. Not a nickel of USDA money was ever put into that work. I was supported by NIH and by NSF, and I think that speaks volumes for the approach.

Mr. **Knutson**. I think there's a basic structural issue here. And that is that normally in most land-grant universities botany and those kinds of areas are not in the school of agriculture and are not a part of the experiment station system. There is no reason they couldn't that I can see. But they have not traditionally been a part of it. And I would guess that you were in a department that was outside of the experiment station system.

Mr. **Fox**. I was in a university where there was no agriculture at all.

Mr. **Knutson**. OK. But that is a problem in the land-grant universities, that some of these departments are in the school of science and have no ties to the experiment station. And that is a line of demarcation that I think is breaking down, but I don't think it is by any means broken down.

Mr. **Brown**. I think it should be pointed out in defense of the Department of Agriculture that they are trying to move through such programs as the competitive grant system into the funding of this, and that the roadblock may well be in the Congress at this particular point rather than in the Department of Agriculture. And I am trying to get that across to some of my colleagues in the Congress so that we can move in partnership with the department and the administration much more aggressively into this field.

I think it will happen. But we are talking here about institutional systems that are a 100 years old where there are staff who were trained in the old school, where there has been stable funding and no opportunity to bring in the amount of new blood that might be required or desirable to cope with rapid change, and you have to accommodate your thinking to this kind of a framework.

I hope that we can, as a result of this hearing and similar activities, be prepared to deal more wisely with these issues.

Mr. Packard?

Mr. **Packard**. Mr. Chairman, I think that there has historically been in our society establishing a level of life priorities—and I don't know hardly how to say it—the human, of course, being at the top of our priority list in terms of evaluating life on this earth, and the animal, perhaps, just below the human level. And the plant has looked to be as an inferior level of life, a less developed level of life than the animal. And below the plant, I don't know where you would go, but nevertheless that is what our mentality has taught us all of our lives and, I guess, historically.

Therefore, we have assumed that research and biotechnology will have less effect upon plants and its productiveness than it has on animals. And obviously our biomedical research has been in advance of our animal biology studies. And I suppose that that is maybe more of a logical reason why we have seen the emphasis and the priorities at the levels and the stages that they are.

And that doesn't justify it——

Mr. **Volkmer**. I would just like to commend the gentleman on quite a philosophical statement.

Mr. **Packard**. And that doesn't justify it. It simply means that maybe we have to look at plant life now as it becomes a priority as we have dealt with animal life in the past.

Mr. **Brown**. It was pointed out by a previous witness that if the Department of Agriculture had been engaged in research programs that preserved the lives of old Congressmen, why, they would have gotten more funding. Possibly, they can come up with a tobacco plant that eats cancer, or something like that.

Mr. **Packard**. Or if the animal in Congress would have been more predominant, as it often is, perhaps maybe that would have changed the priority fundings, too.

Mr. **Brown**. We are getting a little maudlin now.

Let me express my appreciation to both of you gentlemen and to you, Dr. Fox, for remaining beyond the call of duty here. I think all of us found your contribution to be extremely worthwhile, and we appreciate it very much.

With that, the subcommittee will be adjourned until tomorrow at 1 o'clock.

[Whereupon, at 4:42 p.m., the subcommittee was recessed, to reconvene at 1 p.m. the following day.]

BIOTECHNOLOGY AND AGRICULTURE

WEDNESDAY, APRIL 17, 1985

House of Representatives,
Committee on Science and Technology,
Subcommittee on Investigations and Oversight,
Washington, DC.

The subcommittee met, pursuant to call, at 1 p.m., in room 2325, Rayburn House Office Building, Hon. Harold L. Volkmer (chairman of the subcommittee) presiding.

Mr. Volkmer. Good afternoon. Welcome to the second of 2 days of hearings on biotechnology and agriculture. The Subcommittee on Investigations and Oversight will come to order.

And yesterday we heard testimony from the Department of Agriculture and from three private firms concerning the status of their biotechnology research. We learned that in several areas of research significant progress was being made, such as in production of animal growth hormone. In fact, the prediction was made that over the next few years the products of genetic engineering research will have a major impact on agricultural markets.

We also heard witnesses describe potential problems that may arise from ongoing joint university/industry research projects. We heard testimony to the effect that while the advantage of such joint research ventures are great solutions must be worked out to the problems of proprietary rights and other issues or these university/industry projects could be jeopardized.

Today, we are looking forward to hearing testimony in two important areas. First, the impact of regulation on the future of biotechnology; and second, the impact of genetic engineering on agricultural policy.

At this time, I recognize the gentleman from California, if he has any statement that he wishes to make at this time.

At this time, I will call up the first panel, and following that I am going to relinquish the chair to the gentleman from California. He has been very interested in this field for a good many years and, in fact, we are both members of the Agriculture Committee, and I have served on his subcommittee over there, on Government Ops and Research, and he has shown a lead in this issue.

In fact, because of a little laryngitis that I still have, I will do like I did yesterday, and I will sit back and be quiet and let him conduct the hearings.

So, at this time, I would like to have Mr. Edgar Kendrick, Administrator, Office of Grants and Program Systems, U.S. Department of Agriculture; Mr. Steven Schatzow, Assistant Administrator for Pesticides and Toxic Substances, U.S. Environmental Protection

Agency; Dr. Bernadine Healy, Deputy Director, Office of Science and Technology Policy; and Dr. Ralph Hardy, BioTechnica International, Cambridge, MA; and Dr. Jack Doyle, from Environmental Policy Institute, Washington, DC.

Will you all come to the table, and your statements will be made a part of the record. We will begin with Dr. Healy, and I will let Mr. Brown decide how to follow with whomever follows next.

Dr. Healy, you may proceed.

STATEMENTS OF EDGAR KENDRICK, ADMINISTRATOR, OFFICE OF GRANTS AND PROGRAM SYSTEMS, U.S. DEPARTMENT OF AGRICULTURE; STEVEN SCHATZOW, DIRECTOR, OFFICE OF PESTICIDE PROGRAMS, U.S. ENVIRONMENTAL PROTECTION AGENCY; BERNADINE HEALY, M.D., DEPUTY DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, THE WHITE HOUSE; RALPH HARDY, PH.D., BIOTECHNICA INTERNATIONAL, INC., CAMBRIDGE, MA; JACK DOYLE, ENVIRONMENTAL POLICY INSTITUTE, WASHINGTON, DC

Mr. **Volkmer**. You don't have laryngitis, too, do you, Dr. Healy?

Dr. **Healy**. I am afraid I do, Mr. Volkmer.

Mr. Chairman and members of the committee, I am honored to appear before you this afternoon as the chairman of the Cabinet Council on Natural Resources and the Environment Working Group on Biotechnology.

The primary concern of the Working Group has been and continues to be the U.S. environment for research and safe commercial development of biotechnology products. In response to concerns about safety and benefits of commercial biotechnology, the Working Group first considered the regulatory framework affecting the development, use, and disposal of biotechnology products with the goal of assuring the public of their safety and well-being, and at the same time providing industry with a clear path through the regulatory process; one that is free from delays and unnecessary complications that can stifle innovation and the competitive edge in international markets.

The second phase of the Working Group's effort is directed toward issues related to federally sponsored research, long-term educational training for scientists and bioengineers to assure skills necessary for research and commercial scale-up, export requirements for U.S. products and trade barriers, current methods of intellectual property protection and patents, and international agreement on both regulatory and trade issues.

Before focusing on the regulatory environment per se, I would like to make a few general comments. We are currently the world leaders in biotechnology and the basic science that has led to its development. That leadership is not an accident or a genetically determined fact of life; rather, it is because of three major factors:

First, our strong investment in science and technology over the past 30 years.

Second, our human resources. The scientific and technical talent that has been nurtured here and invested in for so long.

And third, the strong effort on the part of industry.

In the recent report from the President's Commission on Industrial Competitiveness, a global question was asked: What are the strengths and weaknesses of the United States with regard to our future economic and industrial leadership? Weaknesses cited were capital costs, monetary exchange rates, cost of labor in the United States, U.S. trade laws, and international trade laws.

In the long list of U.S. strengths and weaknesses for future world competitiveness, there were only two major strengths: our technology base, the technology which propels our economy; and our talent base, the innovation which creates and renews that technology.

Biotechnology is an excellent example of leadership based on those two strengths.

In the same report on industrial competitiveness, pitfalls in American success were cited, and not surprisingly, one very high on the list was a concern about our cumbersome and complex regulatory environment. I quote from the report:

> The net result of our cumbersome and complex regulatory environment has been that innovative products are more easily and quickly introduced abroad. The issue is not whether regulations should exist—their benefits are clear—but improper or ineffective regulation can inhibit innovation.

There are concerns that biotechnology may also be an example of regulations stifling leadership.

One thing is certain. We will never fully control the evolution or the perturbation of our world that is brought about by advances in science and technology. We will try. We will set up mechanisms and processes, write laws and issue regulations, however imperfect, to try and modulate. We have been doing this for over a century. Our general approach has been rather consistent, and I believe rather wise: Placing the applications of new knowledge under public scrutiny and not by denying or hampering the process of experimentation and exploration.

It should be stressed that public scrutiny of the applications of science and technology is not new. Laws restricting the use of dangerous medical procedures and drugs or the introduction of foreign plants or animals in agriculture are older than recombinant DNA. And throughout there has been a central theme of public controlling applications of science and not the science itself.

The Federal Government has clearly accepted major responsibility for the health and environmental consequences of applications of technology, particularly as science and technology emerge in the marketplace with opportunity for broad impact on society. For biotechnology, the incredible benefits to society appear particularly widespread with opportunities for new and better medicines and therapies for disease; better and more efficient food production; a wide range of chemicals for consumer and industrial uses, and even the promise of new sources of energy.

But no one denies the risks accompanying any of these applications, a few real and some imagined. Even imagined or perceived risks lurking below the level of rational argument must be addressed. For biotechnology, there has been little question as to the responsibility and the authority of the Federal Government.

And indeed, the Federal Government already has a good track record in this record. From its inception in 1974, the NIH RAC provided a forum for balancing risks and benefits of this science. The RAC, using a case-by-case approach, developed general guidelines for conduct of recombinant DNA research, its authority quite clear. Any application funded by the NIH had to comply with the NIH review and guidelines. Since most of the basic research was supported by the NIH, the authority was adequate to meet the needs of most research. Coincidentally, virtually all the major companies conducting basic research involving recombinant DNA voluntarily sought the advice of the RAC and complied with its guidelines. And so did most foreign countries.

Thus, the NIH RAC has served as the respected scientific authority for risk review of laboratory-based recombinant DNA activities. It has functioned so well that it acquired an erroneous reputation as a regulatory body. Yet, the RAC never ceased to be any more than a scientific advisory body.

And so, to return to our Cabinet Council effort, its focus has been to define the regulatory environment for balancing risks and benefits.

The Working Group operated under several premises. First, that biotechnology provides the opportunity for a vast array of products and the economic, health and environmental benefits that accompany their use. Second, that the safety of new application of biotechnology must be adequately assessed. Third, that the United States is currently the world leader in biotechnology largely because of the U.S. investment in basic research, and that it should maintain that leadership as biotechnology is commercialized.

Real or perceived regulatory uncertainties pose the double risk of adversely affecting the climate for innovation and leadership in industry and creating concerns in the public that their safety is not being adequately protected.

Accordingly, our first task was to outline a coordinated interagency framework for regulation of biotechnology. That initial effort is summarized, as you know, in the Federal Register notice of December 31, 1984. The notice consists of three major sections. The first is a matrix describing existing laws, regulations and guidelines that may be applicable to biotechnology products and processes. These are shown as they apply at each point in the sequence of research, development, manufacturing, marketing, shipping, and disposal. The 19-page table might alone suggest that there is abundant Federal authority to regulate biotechnology. But after many months of discussion and review, the Cabinet Council group concluded that for now—and I stress for now—the existing laws were adequate for biotechnology in its current phase.

The second part of the December 31 notice contains policy statements by EPA, USDA, and FDA. These statements attempt to provide a clearer understanding of how the regulatory agencies will approach this emerging field, and there are some common themes across the agencies.

The first step outlined in all of the policies is to determine agency authority to regulate in a given area. That determination is based, for the most part, upon the uses of the product. Usually that is a simple decision. Is it to be used as a drug, a device, a pesticide, an animal biologic, or a household and industrial chemical?

Overlaps must be settled. For example, does a human gene therapy investigation supported by NIH funds need to be reviewed by the NIH RAC or by the FDA under an investigational new drug application? It is expected that there will be in some cases overlapping authority, and this is clearly an example. Here the need for a well-defined mechanism for interagency coordination becomes evident.

Another common feature of the policy statements is that all three agencies will approach the review of biotechnology products on a case-by-case basis, employing both internal staff and expert advisory committees. With such approach agencies will develop expertise with these products and a scientific data base that will facilitate subsequent review of other products of similar types and similar uses.

Using a case-by-case approach, they will in time develop generic guidelines based on experience and not abstract concerns. Again, communication and coordination across agencies on their historic experience, particularly for similar products under several agencies' jurisdiction, is important to a streamlined system. Hence, a vital part of the notice is that EPA, FDA, and USDA are committed to working together and, with the other members of the Cabinet Council Working Group, to coordinate both scientific evaluation and administration procedures for biotechnology.

The obvious next question is how does one institutionalize the commitment on the part of the varying agencies with different missions and different agendas to coordinate their efforts on decision making, both with regard to scientific assessment of safety and benefit and also with regard to the administrative procedures involved in decision making?

We have proposed a two-component structure to accomplish this. A scientific advisory mechanism that is knit together by a strong interagency parent broad that evaluates science and safety. The second is an interagency coordinating committee, separate from the scientific structure, which focuses on risk management and regulation.

With regard to the scientific advisory mechanism, we believe something new must be developed. If there is any inadequacy in our Federal structure, it is clearly in the availability of a scientific review mechanism that can deal with the broad range of commercial products now arising—now emerging on the horizon. The NIH RAC is neither equipped nor desirous of taking on that role on a Government-wide basis. Although much of the science that underlies review of commercial or agricultural products is the same, the NIH RAC is oriented toward basic biomedical research and not commercial scale-up, and has limited environmental and ecological experience. Nevertheless, a central core of scientific expertise for all the agencies would promote consistent assessments of risk key to any final risk/benefit analysis and key to a streamlined and consistent Federal approach to biotechnology.

Accordingly, we proposed a two-tiered scientific structure in which there are five agency-based committees under a strong coordinating parent board, composed primarily, but not exclusively, of members of the agency-based committees. These agency-based committees will provide the daily detailed case-by-case scientific review of applications, and would respond fully to the needs of their own agencies with regard to time constraints and proprietary as well as security procedures.

The parent board would be centrally located, would be informed of reviews being conducted by the other agencies, would review the final reports, and would, in time, be the group which develops needed generic scientific guidelines that can be applied to similar applications received by the various agencies.

The parent group would also be the forum for quality control of review, and for discussion of board scientific concerns. For example, broad issues related to exchange of genetic material across species is of concern to the NIH, to the FDA, to the USDA, at the very least, and an in-place interagency scientific panel would be equipped to bring to bear the varied concerns and perspectives of the somewhat different scientific communities represented in our different agencies.

This scientific advisory mechanism is, however, advisory. It is geared to provide scientific assessment of risk and suggest guidelines for minimizing risk. It provides necessary input to the regulatory process, but it does not make the regulatory decisions; nor does it make the final assessment on balancing risks with those benefits. The latter is the responsibility of the agencies under the authority granted to them by the law.

The second coordinating structure proposed in the notice is an interagency regulatory coordinating body. The Cabinet Council Working Group endorsed the establishment of such a group to foster coordinated decisionmaking by regular interagency communication.

This committee would also discuss issues of jurisdiction among agencies, serve as a forum whereby agencies can raise both public and industry concern and, importantly, consider general approaches for balancing risks and benefits and for translating risk assessment information into policy decisions.

The Working Group believes that existing authorities are adequate to deal with the products now emerging from modern biotechnology, but recognize, again, the need for an ongoing mechanism to monitor the changing scene and make appropriate recommendations for legislation or administrative action if inadequacies arise. At the present time, the Cabinet Council Working Group can serve these needs.

At the close of the public comment period, which was Monday, April 15, the Office of Science and Technology Policy alone received a total of 85 comments: 21 from industry, 20 from industrial and professional associations, 23 from university faculty and administrators, 6 from Government scientists, 6 from public interest groups, 1 from a nonprofit research institute, 1 from a Member of Congress, 3 from international sources, 1 from an interested citizen, and 3 from law firms. Other comments were sent to EPA, USDA, and FDA. The following summary represents only those comments received by Friday, April 12.

Virtually all commended the work of the Working Group in the attempt to clarify the regulatory process. In general, there has been no support for additional legislation to regulate research, development, production, use or disposal of biotechnology products, as of the April 12 tally.

Industry expressed some concern about the time and cost of complying with the regulatory process. It recognizes the need for scientific advisory mechanism, but there has been concern about any delay in the regulatory process that a two-tiered review body might involve.

University and other sources expressed similar concerns about costs and delays. Several commentators noted the need for the advisory mechanism to include members from public interest groups, industry, and other nonscientists. There were several suggestions for alternative structures for the scientific review mechanism, all of which I must say the Working Group had considered. Several endorsed the Working Group's attention to international corporation.

The Working Group plans to study the comments in great detail, make appropriate changes, and publish a final document as soon as possible.

I would like to stress in closing that the effectiveness of that regulatory framework, however, ultimately lies in those that give it life: The agencies that are committed to working with each other as they carry out their own responsibilities; the industries that are committed to good faith dealings with the agencies and with the public; and the public itself which comes to trust that the many benefits of biotechnology will be realized only in the context of their safety to health and to the environment.

It is the goal of the Working Group and the administration to remove any existing or future roadblocks to this exciting, emerging industry by implementing Federal policies that will support basic research and training and enhance the competitiveness of U.S. industry in both domestic and international markets.

Thank you.

[The prepared statement of Dr. Healy follows:]

Statement of
Bernadine Healy, M.D.
Deputy Director
Office of Science and Technology Policy
Executive Office of the President

Before the
Committee on Science and Technology
Subcommittee on Investigations and Oversight

April 17, 1985

Mr. Chairman and members of the Committee, I am honored to appear before you this afternoon as the Chairman of the Cabinet Council on Natural Resources and the Environment Working Group on Biotechnology. The primary concern of the Working Group has been and continues to be the U.S. environment for research and safe commercial development of biotechnology products. In response to concerns about safety and benefits of commercial biotechnology the Working Group first considered the regulatory framework affecting the development, use, and disposal of biotechnology products with the goal of assuring the public of their safety and well-being and at the same time providing industry with a clear path through the regulatory process--one that is free from the delays and unnecessary complications that can stifle innovation and the competitive edge in international markets. The second phase of the Working Group's effort is directed towards issues related to federally sponsored research, long-term educational training for scientists and bioengineers to assure skills necessary for research and commercial scale-up, export requirements for U.S. products and trade barriers, current methods of intellectual property protection and patents, and international agreement on regulatory and trade issues.

Before focusing on the regulatory environment per se, I would like to make a few general comments.

We are currently the world leaders in biotechnology--and the basic science that led to its development.

That leadership is not an accident or a genetically determined fact of life--rather it is because of three major factors:

- our strong investment in science and technology over the past 30 years;
- our human resources--the scientific and technical talent that has been nurtured here and invested in for so long;
- strong efforts on the part of industry.

In the recent report from the President's Commission on Industrial Competitiveness, a global question was asked--what are the strengths and weaknesses of the U.S. with regard to our future economic and industrial leadership?

Weaknesses cited were capital costs, monetary exchange rates, cost of labor in the U.S., U.S. trade laws and international trade laws.

In the long list of U.S. strengths and weaknesses for future world competitiveness, there were only two major strengths:

- our technology base--the technology which propels our economy;
- our talent base--the innovation which creates and renews technology.

Biotechnology is an excellent example of leadership based on those strengths.

In the same report on Industrial Competitiveness pitfalls in American success were cited and, not surprisingly, one high on the list was a concern about our cumbersome and complex regulatory environment. I quote from the report, "The net result of our cumbersome and complex regulatory environment has been that innovative products are more easily and quickly introduced abroad. The issue is not whether regulations should exist--their benefits are clear--but improper or ineffective regulation can inhibit innovation." There are concerns that biotechnology may also be an example of regulation stifling leadership.

One thing is certain. We will never fully control the evolution or perturbation of our universe that is brought about by advances in science and technology. We will try, we will set up mechanisms and processes, write laws and issue regulations, however imperfect, to try to modulate. We have been doing this for over a century. Our general approach has been rather consistent and rather wise--placing the applications of new knowledge under public scrutiny, not by denying or hampering the process of experimentation and exploration.

It should be stressed that public scrutiny of the applications of science and technology is not new. Laws restricting use of dangerous medical procedures and drugs or on introduction of foreign plants or animals in agriculture are older than recombinant DNA. And throughout there has been a central theme of the public controlling applications of science and not science itself.

The Federal Government has clearly accepted major responsibility for the health and environmental consequences of applications of technology, particularly as science and technology emerge in the marketplace with opportunity for broad impact on society. For biotechnology the incredible benefits to society appear particularly widespread with opportunity for new and better medicines and therapies for disease, better and more efficient food production, a wide range of chemicals for consumer and industrial uses, and even the promise of new sources of energy. But no one denies the risks accompanying any of these applications, a few real and many imagined. Even imagined or perceived risks lurking below the level of rational argument must be addressed. For biotechnology there has been little question as to the responsibility and authority of the Federal Government.

Although Avery linked DNA to heredity in the 1940's, it was only 12 years ago that DNA from one organism was recombined in a directed fashion using splicing enzymes with that of another organism to create, so to speak, a new life form. This man-made transformation of living organisms in the research laboratory was almost immediately recognized for its great commercial potential and potential for wide-ranged societal benefit; but, scientists themselves cautioned about possible risks. The subsequent series of conferences and the formation of the NIH Recombinant DNA Advisory Committee are widely acclaimed.

From its inception in 1974 the RAC provided a forum for balancing risks and benefits of this science. The RAC, using a case by case approach, developed general guidelines for conduct of rDNA research--its authority quite clear. Any application funded by the NIH had to comply with the NIH review and guidelines. Since most of the basic research was supported by NIH, the authority was adequate to meet the needs of most research. Coincidentally, virtually all the major companies conducting basic rDNA research voluntarily sought the advice of the RAC and complied with its guidelines. And so did most foreign countries. Thus the NIH RAC has served as the respected scientific authority for risk review of laboratory based rDNA activities. It has functioned so well that it acquired an erroneous reputation as a regulatory body. Yet the RAC never ceased to be any more than a scientific advisory body.

And so, to return to our Cabinet Council effort, its focus has been to define the regulatory environment for balancing risks and benefits with risks defined primarily as accidental occurrences, and, to a lesser extent, also those which are incidental.

The Working Group operated under several premises. First, that biotechnology provides the opportunity for a vast array of products and the economic, health and environmental benefits that accompany their use. Second, that the safety of new application of biotechnology must be adequately assessed. Third, that the United States is currently the world leader in biotechnology largely because of the U.S. investment in basic research and that it should maintain that leadership as biotechnology is commercialized. Real or perceived regulatory uncertainties pose the double risks of adversely affecting the climate for innovation and leadership in industry and creating concerns in the public that their safety is not being adequately protected.

Accordingly, our first task was to outline a coordinated interagency framework for regulation of biotechnology. That initial effort is summarized in the Federal Register notice of December 31st. The notice consists of three major sections. The first is a matrix which describes existing laws, regulations, and guidelines that may be applicable to biotechnology products and processes. These are shown as they apply at each point in the sequence of research, development, manufacturing, marketing, shipping, and disposal. The 19-page table might alone suggest that there is abundant federal authority to regulate biotechnology. But, after many months of discussion and review the Cabinet Council group concluded that for now the existing laws were adequate for biotechnology.

The second part of the December 31 notice contains policy statements by EPA, USDA, and FDA. These statements attempt to provide clearer understanding of how regulatory agencies will approach this emerging field, and there are some common themes across agencies.

The first step outlined in all the policies is to determine agency authority to regulate in a given area. That determination is based for the most part upon uses of the products. Usually that is simple--is it to be used as a drug, a device, a pesticide, an animal biologic, or a household or industrial chemical. Overlap must be settled. For example, does a human gene therapy investigation which is supported by NIH funds need to be reviewed by the NIH RAC and also by the FDA under an investigational new drug (IND) application? It is expected that there will be in some cases overlapping authority. And, here, the need for a well defined mechanism for interagency coordination becomes evident.

Another common feature of the policy statements is that all three agencies will approach the review of biotechnology products and processes on a case-by-case basis, employing both internal staff and expert advisory committees. With such an approach agencies will develop expertise with these products and a scientific data base that will facilitate subsequent review of other products of similar types and uses. Using a case-by-case approach, they will in time develop generic guidelines based on experience and not abstract concerns. Again communication and coordination across agencies on their historical experience, particularly for similar products under several agencies' jurisdiction, is important to a streamlined system. Hence, a vital part of the notice is that EPA, FDA and USDA are committed to working together and with the other members of the Cabinet Council Working Group to coordinate both scientific evaluation and administration procedures for biotechnology.

The obvious next question is how does one institutionalize the commitment on the part of several different agencies with different missions and different agendas to coordinate their efforts on decision making, both with regard to the scientific assessments of safety and benefits and with regard to the administrative procedures involved in decision making?

We have proposed a two-component structure to accomplish this. One is a scientific advisory mechanism that is knit together by a strong interagency parent board that evaluates science and safety. The second is an interagency coordinating committee on risk management and regulation.

With regard to the scientific advisory mechanism we believe something new must be developed. If there is any inadequacy in our federal structure it is in the availability of a scientific review mechanism that can deal with the broad range of commercial products now emerging and on the horizon. The NIH RAC is neither equipped nor desirous of taking on that role on a government-wide basis. Although much of the science that underlies review of commercial or agricultural products is the same, the NIH RAC is oriented towards basic biomedical research and not commercial scale up, and has limited environmental and ecologic expertise. Nevertheless, a central core of scientific expertise for all the agencies would promote consistent assessments of risks key to any final risk/benefit analysis and key to a streamlined and consistent federal approach to biotechnology.

Accordingly, the working group proposes a two-tiered scientific advisory structure with five agency-based committtees (EPA, FDA, USDA, NIH RAC and NSF) under a strong coordinating parent board composed primarily of members of the agency-based committees. These agency-based committees would provide the detailed case-by-case scientific review of applications and would respond fully to the needs of their agencies with regard to time constraints and proprietary and security procedures.

The parent board would be centrally located, would be informed of reviews being conducted by the agency committees, would review the final committee reports, and would, in time, be the group which develops generic scientific guidelines that can be applied to similar applications received by the various agencies. The parent group would also be the forum for quality control of review and for discussion of broad scientific concerns. For example, broad issues related to exchange of genetic material across species is of concern to NIH, FDA, and USDA, at the least, and an in-place interagency scientific panel would be equipped to bring to bear the varied concerns and perspective of the somewhat different scientific communities represented in the different agencies.

This scientific advisory mechanism is, however, advisory. It is geared to provide scientific assessment of risk, and suggest guidelines for minimizing risk. It provides necessary input to the regulatory process, but it does not make the regulatory decisions, nor does it make the final assessments on balancing risks and benefits. The latter is the responsibility of the agencies under the authority granted to them by law.

The second coordinating structure proposed in the notice is an interagency regulatory coordinating body. The Cabinet Council Working Group endorsed the establishment of such an interagency coordinating committee on biotechnology regulation to foster coordinated decision making by regular interagency communication. This committee would also discuss issues of jurisdiction among agencies, serve as a forum by which agencies can raise public and industry concern; and, importantly consider general approaches for balancing risks and benefits, and for translating risk assessment information into policy decisions. The Working Group believes that existing authorities are adequate to deal with the products now emerging from modern biotechnology, but recognize, again, the need for an ongoing mechanism to monitor the changing scene and make appropriate recommendations for legislation or administrative action if inadequacies arise. At the present time the Cabinet Council Working Group can serve these needs.

At the close of the public comment period on April 15 the Office of Science and Technology Policy received a total of 85 comments: 21 from industry, 20 from industrial and professional associations, 23 from university faculty and administrators, 6 from government scientists, 6 from public interest groups, 1 from a nonprofit research institute, 1 from members of Congress, 3 from international sources, 1 from an interested citizen, and 3 from law firms. Comments were also sent to EPA, USDA, and FDA. The following summary represents only those comments received by by Friday, April 12. All commended the efforts of the Working Group to clarify the regulatory process. Among all the comments reviewed on or before April 12, there has been no support for additional legislation to regulate research, development, production, use, or disposal of biotechnology products. Industry expressed some concern about the time and cost of complying with the regulatory process. It recognized the need for a scientific advisory mechanism, but was concerned about any delay in the regulatory process that such a review might entail. University and other sources expressed similar concerns about costs and delays. Several commentors noted the need for the advisory committees to include members from public interest groups, industry, and other nonscientists. There were several suggestions for alternative structures for the scientific review mechanism--all of which the Working Group had considered. Several endorsed the Working Group's attention to international cooperation.

The Working Group plans to study the comments in great detail, make appropriate changes and publish a final document as soon as possible.

I would like to stress in closing that the effectiveness of the regulatory framework, however, ultimately lies in those that give it life: the agencies that are committed to working with each other as they carry out their own responsibilities; the industries that are committed to good faith dealings with the agencies and with the public; and the public itself which comes to trust that the many benefits of biotechnology will be realized only in the context of their safety to health and the environment.

It is the goal of the Working Group and the Administration to remove any existing or future roadblocks to this exciting, emerging industry by implementing Federal policies that will support basic research and training and enhance the competitiveness of U.S. industry in both domestic and international markets.

Mr. **Brown**. Thank you very much, Dr. Healy.

I think we will proceed with the other members of the panel and then have questions en bloc.

Mr. Schatzow, do you care to proceed now?

Mr. **Schatzow**. Thank you, Congressman Brown. I might state for the record that I appreciate the promotion that the committee gave me. Actually, my boss, Jack Moore, is the Assistant Administrator for Pesticides and Toxic Substances. I am just the office director for the Office of Pesticide Programs.

Mr. **Brown**. We didn't raise your salary, we just changed your title.

Mr. **Schatzow**. That's right. There are no salary raises.

I'm pleased to be here today. I'm going to try to skip through some of my testimony. I'll leave it—it's submitted for the record, if the chairman would prefer. Would you like me to try to summarize? Would that be helpful?

Mr. **Brown**. It would be helpful. The full text will appear in the record however.

Mr. **Schatzow**. Thank you.

I'm very pleased to be here to talk about what EPA is doing under FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act—as it relates to genetically altered or nonindigenous microbial pesticide products. I think that Dr. Healy has summarized very well what's in part of our testimony in terms of the Cabinet Council Working Group, which Dr. Moore has been a member of, and in terms of the public reaction to that general notice.

A number of months prior, in fact, in October 1984, EPA published an earlier Federal Register notice which established interim procedures for notification to EPA prior to small-scale field testing of genetically altered or nonindigenous microbial pesticide products. We received only a very limited number of comments on that interim policy, and those comments were primarily from researchers and from people within the pesticide industry, who indicated general support for the interim policy but who expressed concern about confidentiality of the information on their organisms and on their planned experiments, and who also expressed some concern about potential delays that might take place as a result of the notification procedure.

The—what we have proposed in both of the policy statements is to continue for the time being the evaluation of genetically altered pesticides on a case-by-case basis under our existing regulatory mechanisms. As we have indicated to this subcommittee on previous occasions, we believe that the current pesticide regulatory framework is adequate to handle pesticide products of biotechnology. And our current approach is consistent with the Cabinet Council's desire that the Federal Government utilize a coherent and sensible regulatory process which is based on the best available science.

In the long—in terms of long-term goals, we are focusing on developing more explicit procedures and requirements for evaluating genetically engineered pesticides, and these types of goals include identifying additional testing that may be routinely needed to accomplish adequate regulation and subsequently modifying our already existing microbial pesticide data requirements, test guidelines, and regulatory polices and procedures as necessary.

To supplement these activities, I should note that EPA's Office of Research and Development is conducting a variety of research to help develop the—and to deal with the potential human health and environmental consequences of the release of genetically altered microorganisms in the environment. ORD has already sponsored workshops to try to identify issues where knowledge is lacking, and it appears that although considerable information already exists which is relevant to the evaluation of microbials, the real emphasis which we are expecting to get from the research community in the next years will be in terms of the issue of the ability of these microbials to spread into the environment and the ecological consequences of the deliberate release of microbial organisms.

Now, in developing our proposed policies and review mechanisms we have drawn heavily upon years of experience in regulating naturally occurring microbial pesticides. Today there are 14 microbial pesticides registered in over 100 products for use in agricultural and domestic settings, forestry, and mosquito control. They include, for instance, the pesticide *Bacillus popilliae,* which consists of naturally occurring bacteria which produce milky spore disease in Japanese beetle larvae and their subsequent death. The bacteria, which are non-toxic to humans and other insect species, are applied to turf and can persist in soil for several years, thus providing lasting insect control.

The most widely used microbial, *Bacillus thuringiensis,* is registered for use on approximately 40 crops and sites. When consumed by larvae of butterflies and moths who feed on treated vegetation, it produces a toxin in the stomach of the insect resulting in death.

It is important to note that these EPA-registered, naturally occurring microbials are usually very selective for certain pests and that to date no serious adverse human health or environmental effects have been associated with the use of these microbials. Further, all registered microbials have been exempted from a requirement for tolerances due to their lack of toxicity to humans.

Now, the microbials that we have registered often exhibit many of the same traits as those which are engineered or otherwise manipulated by humans, and therefore the existing microbial data requirements and test guidelines will generally apply to genetically altered microbials, although it is likely that we will have, on a case-by-case basis, to require additional data to fully assess their effects. And in fact, our data requirements are part 158 data requirements, do give us the flexibility to require such additional data.

Since we last testified before this subcommittee, about 2 years ago, there have been significant strides in developing genetically altered microbial pesticides. We no longer need to speculate as to when such pesticides will be regulated by EPA. In fact, several companies and independent researchers are ready to field test organisms in the open environment. Since publication of our interim policy in October, we have received five notifications for field testing.

Now, the—what the interim policy in general terms require is it requires the company to—or the individual who is interested in field testing a genetically altered or nonindigenous microbial to submit a notification to EPA of its plans and to submit a variety of information about the microbial and the aspects of the microbial. From the time that EPA receives this notification, EPA has 90 days to evaluate the proposed testing. If the Agency decides that the project raises environmental or health concerns, we may require the company to obtain an experimental use permit [EUP] before the testing can proceed.

The decision to require such an EUP will ensure that testing will be conducted in a manner least likely to result in unreasonable adverse effects on the environment. In particular, by requiring an EUP and requiring clear process for testing and information up front, and monitoring of the testing itself, we will assure that the Agency has sufficient information to make the requisite risk assessment that any further experiments will provide the type of information needed for subsequent regulatory decisionmaking. We will assure that the results of such experiments and the actual tests are reported to EPA, and that sufficient oversight of the tests by EPA will be possible.

When additional data development is required before an EUP can be issued, the types of information required should be supportive of future product registration. I want to make it clear this requirement, the notification requirement is only applicable to testing in the environment. It does not apply where there is no direct release to the environment, to experiments conducted in growth chambers or in contained laboratories, and greenhouses or similar facilities.

Now, although EPA does not usually require EUP's—experimental use permits—for such small-scale field testing of conventional pesticides, which have no independent mobility and reproductive capability, we have and will in a number of cases require EUP's for small-scale testing of microbials which are genetically altered or which are nonindigenous. And that is, as I mentioned before, because of our concern that such microbials may replicate and spread beyond the site of the application with potential adverse effects. And further, that they may not be subject to natural control or dissipation.

Among other things, for instance, they could exhibit a greater competitiveness, a broader host range, production of a new toxin, or enhanced virulence. Consequently, they might be difficult to control or eradicate after being introduced into the environment. Therefore, the notification requirements are designed to address these types of questions while resulting in only a small delay in the development of beneficial microbial pesticides for use in the agricultural community.

We have thus far received five notifications. We have completed our evaluation of three. The fifth notification has been voluntarily withdrawn by the submitter. The first two that we evaluated were microbial pesticides containing non-ice nucleating bacteria to be tested on strawberries, potatoes, snap beans and, ah, and tomatoes. That's twice on tomatoes; lots of tomatoes. [Laughter.]

Naturally occurring bacteria can help to precipitate frost formation on plants and trees. And the developers of the products in question have genetically altered the bacteria so they lack the ability to promote frost. They occupy the same ecological niche as their natural counterparts and may be able to compete with and displace their natural form in agricultural fields, thereby protecting plants from frost formation, especially when the weather turns unusually cold out of season. Availability of such a product could prevent the significant economic loss experienced by growers whose crops are ruined by unusual weather conditions.

The third product which was fully evaluated under the interim policy entails insertion of a gene into a common type of soil bacterium, which causes the bacterium to make an insect toxin; that is, it produces its own insecticide. The gene which has been inserted comes from the common bacterium *Bacillus thuringiensis,* which I discussed earlier, and has been widely tested for many years. The developers wish to field test this product to determine its effectiveness against certain soil-dwelling insects.

The fourth notification is one from USDA, and it is still under evaluation. This proposed product contains strains of a fungus which has been altered by undirected mutagenesis using both ultraviolet radiation and chemical treatment in order to provide increased effectiveness against a variety of types of fungi.

In each of the three reviews that we have completed thus far, the Agency has determined that an EUP will be necessary to address unanswered questions about the effects of the organisms in the environment. A critical question to be answered in the EUP process relates to the ability of the organisms to replicate and spread beyond the application site. Although we believe that the unanswered questions do not necessarily support the contention that these products may pose a high risk, we believe that it is prudent to now require additional testing in order to properly evaluate those potential risks.

I will speak briefly here about the process that we—the evaluation process we have developed to try to deal with the notifications. It's a fairly hectic enterprise trying to complete the evaluation within a 90-day period. What we've done is to develop, first of all, an internal review of the notification when it comes in, both by the Office of Pesticide Programs and then by other parts of EPA including our Office of Research and Development and our Office of Toxic Substances.

Once we have completed our internal Agency review, we then take our recommendations to a sub-panel of our legislatively mandated Scientific Advisory Panel [SAP]. And the SAP sub-panel, in fact, the members to deal with each of the applications are specifically chosen based on the type of notification we've received. Based on the types of issues that are raised by that particular notification. And so these, the peer reviewers are given copies of both the notification and of the internal EPA evaluation. They are asked to comment generally, they are also asked a series of specific questions that we would like them to deal with. They meet; they respond to the Agency. And we, in other situations, may also very well use other Federal agencies such as USDA and FDA, and their experts, to help us. When we have completed our evaluation, we then inform the submitter of our findings and of what future requirements there will be in order to do any field testing.

We feel thus far these procedures have served us well. We have been able to respond in detail to each of the notifications within the 90-day period. I am sure, however, that as we continue that we will have to evolve more, somewhat more sophisticated techniques as the applications descend upon us.

That completes my prepared statement, Mr. Chairman. I'd be happy to answer questions later.

[The prepared statement of Mr. Schatzow follows:]

STATEMENT OF
STEVEN SCHATZOW
DIRECTOR, OFFICE OF PESTICIDE PROGRAMS
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

APRIL 17, 1985

Good afternoon, Mr. Chairman and members of the Subcommittee. I am pleased to be here today to discuss with you the current status of the regulation of genetically altered or non-indigenous microbial pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Before discussing the specific actions EPA is taking to regulate genetically altered microbial pesticide products, I want to note generally that recent developments in biological sciences have greatly enhanced scientists' ability to manipulate genetic material and to develop new microorganisms, plants and animals. These advances might lead to the availability of a variety of useful products in a wide range of industries, including agriculture, chemical production, and environmental protection. However, as with any new process, there are questions about the human health and environmental implications of developing and using microorganisms for commericial purposes. This is of particular concern when their use involves release to the environment where they have not existed before and where natural mechanisms for controlling their populations may not exist.

To address these concerns, EPA is implementing a regulatory framework under existing mechanisms in the FIFRA for reviewing certain pesticide products developed through biotechnology. EPA's proposed regulatory scheme for genetically altered or non-indigenous microbial pesticide products was described in two Federal Register notices published last year. The first notice, published in October 1984, established interim procedures for notification to EPA prior to small scale field testing of such products. The second, published in December 1984 by the Office of Science and Technology Policy (OSTP), proposed EPA's overall plans for regulating such pesticides as part of a coordinated Federal effort.

The Agency received only a limited number of comments on the interim policy -- primarily from researchers and the pesticide industry who indicated support for the concept of the interim policy, but consistently expressed concern about confidentiality of information on their organisms and planned experiments. We hope to receive additional feedback on the interim policy through the second, more comprehensive notice published by OSTP in December.

The comment period on the OSTP notice has just closed. Thus far, EPA has received nearly 75 comments on its proposed regulatory approach outlined in the OSTP notice. These comments will be carefully evaluated in light of the fruits of our experience under the interim policy to further define our regulatory approach, to ensure that it is consistent with the overall federal policy, and most importantly, that it is fully protective of health and the environment.

Many, including the Congress, have expressed concern about the need for a coherent overall Federal approach to regulating products of biotechnology. To respond to this concern, in early 1984, the Cabinet Council on Natural Resources and the Environment established a working group to examine ways to provide a unified federal framework for evaluating and regulating products of biotechnology which would ensure that related health and environmental concerns are addressed while not unduly precluding society from reaping the benefits of biotechnology.

Dr. John A. Moore, EPA's Assistant Administrator for the Office of Pesticides and Toxic Substances (OPTS), actively represents EPA on this group. Initially, the group focused on identifying existing laws and regulations applicable to biotechnology; clarifying the regulatory pathways a new product must follow to meet various federal health and safety requirements; determining the adequacy of those regulatory mechanisms; and recommending additional mechanisms if needed. The findings and recommendations of this group were the genesis of the OSTP notice published in December. In addition to general federal oversight issues, the notice contains individual policy statements developed by EPA, FDA, and USDA, the Agencies most extensively involved in oversight of biotechnology products.

In the EPA regulatory policy statement, the Agency proposed to continue, for the time being, evaluation of genetically altered pesticides on a case-by-case basis under existing regulatory mechanisms. As we have indicated to this Subcommittee on previous occasions, at this time we believe the current pesticide regulatory framework is adequate to handle pesticide products of biotechnology. Moreover, our current approach is consistent with the Cabinet Council's desire that the federal government utilize a coherent and sensible regulatory process which is based on the best available science.

In the way of long-term goals in this area, EPA is focusing on developing more explicit procedures and/or requirements for evaluating genetically engineered pesticides. These include identifying additional testing routinely needed to accomplish adequate regulation, and subsequently modifying microbial pesticide data requirements, test guidelines, and regulatory policies and procedures.

To supplement these activities, I should note that EPA's Office of Research and Development (ORD) is conducting research for the Office of Pesticides and Toxic Substances in the area of biotechnology to address generally the possible human health and environmental consequences of the release of genetically altered microorganisms in the environment. ORD has already sponsored workshops of scientific experts from academia, industry and government to identify the major areas where knowledge is lacking. The consensus of the experts at these workshops was that considerable information already exists which is relevant to the evaluation of microbials including genetically altered microbes. In addition, EPA's Science Advisory Board has formed a subcommittee to evaluate biotechnology research needs across the Agency.

In developing its proposed policies and review mechanisms, EPA drew heavily upon years of experience in regulating naturally occuring microbial pesticides. Today, there are 14 microbial pesticides (including bacteria, protozoa, viruses, and fungi) registered in over 100 products for use in agricultural and domestic settings, forestry and mosquito control. For example, the pesticide, Bacillus popilliae, consists of naturally occurring bacteria which produce milky spore disease in Japanese beetle larvae and their subsequent death. The bacteria, which are non-toxic to humans and other insect species, are applied to turf and can persist in soil for several years thus providing lasting insect control. The most widely used microbial, Bacillus thuringiensis, is registered for use on approximately forty crops and sites. When consumed by larvae of butterflies and moths who feed on treated vegetation, it produces a toxin in the stomach of the insect resulting in death. It is important to note that EPA-registered naturally occurring microbials are usually very selective for certain pests, and that to date, no serious adverse human health or environmental effects have been associated with the use of these microbials. Further, all registered microbials have been exempted from the requirement for tolerances (maximum allowable residues levels on commodities) due to their lack of toxicity to humans.

These microbials often exhibit many of the same traits as those which are engineered or otherwise manipulated by humans. Though existing microbial data requirements and test guidelines would apply also to genetially altered microbials, it is likely that EPA will have to, on a case-by-case basis, request additional data to fully assess their effects. EPA's data requirements explicitly give us the flexibility to require such additional data.

Since EPA testified before this Subcommittee on the subject of biotechnology regulation nearly two years ago, there have been significant strides in developing genetically altered microbial pesticides. We no longer need to speculate as to when such pesticides will be regulated by EPA. Several companies and independent researchers are ready to field test organisms in the open environment. Since publication of our interim policy on the small scale field testing of genetically altered microbial pesticides, EPA has received five notifications for field testing. Regulation of such products has thus become a reality.

The interim policy on small scale field testing (less than 10 acres) was EPA's first formal action under the FIFRA geared solely to regulating genetically altered or non-indigenous microbial pesticides. In general terms, the interim policy describes what types of information companies should include in the notification. From the date of receipt of the required notification, EPA has 90 days to evaluate the proposed testing. If EPA decides that the project raises environmental or health concerns, the Agency may require the company to obtain an Experimental Use Permit (EUP) before the testing can proceed. The decision to require an EUP would ensure that testing will be conducted in a manner least likely to result in unreasonable adverse effects on the environment. In particular, requiring an EUP can ensure that 1) the Agency has sufficient information to make the requisite risk assessment; 2) any further experiments will provide the type of information needed for subsequent regulatory decision-making; 3) the results of further experiments and the actual tests are reported to EPA and 4) sufficient oversight of the tests by EPA is possible. When additional data development is required before an EUP can be issued, the types of information required also would be supportive of future product registration. (It should be noted that this policy does not apply to studies conducted where there is no direct release to the environment, such as in growth chambers, contained laboratories, greenhouses, or similar facilities.)

EPA does not usually require EUP's for small scale field testing of conventional pesticides, which have no independent mobility and reproductive capability, and thus, are unlikely to cause unreasonable adverse effects outside their application area. However, as I mentioned earlier, EPA is concerned that non-indigenous and/or genetically altered microbial pesticides may replicate and spread beyond the site of application with potential adverse effects. Further, they may not be subject to natural control or dissipation. Among other things, they could exhibit a greater competitiveness, a broader host range, production of a new toxin, or enhanced virulence. Consequently, they might be difficult to control or eradicate after being introduced into the environment.

The notification requirements are designed to address these questions, while resulting in only a small delay on the development of beneficial microbial pesticides for use in the agricultural community.

Thus far, EPA has completed evaluation of three of the five notifications submitted. It should be noted that the fifth notification has been voluntarily withdrawn by the submitter pending development of additional data.

The first two pesticides fully evaluated under the interim policy are two microbial pesticides containing non ice nucleating bacteria to be tested on strawberries, potatoes, snap beans, and potatoes. Naturally occurring bacteria help precipitate frost formation on plants and trees. The developers of the products in question have genetically altered the bacteria so they lack the ability to promote frost. They occupy the same ecological niche as their natural counterparts and may be able to compete with and displace their natural form in agricultural fields, thereby protecting plants from frost formation, especially when the weather turns unusually cold out of season. Availability of such a product could prevent the significant economic loss experienced by growers whose crops are ruined by unusual weather conditions.

The third product fully evaluated under the interim policy entails insertion of a gene into a common type of soil bacterium which causes the bacterium to make an insect toxin; that is, it produces its own insecticide. The gene which has been inserted comes from the common bacterium, Bacillus thuringiensis, which as I noted earlier has been registered and widely used for several years. The developers wish to field test this product to determine its effectiveness against certain soil-dwelling insects.

A notification from USDA is still under evaluation. The proposed product contains strains of a fungus altered by undirected mutagenesis using ultraviolet irradiation and chemical treatment in order to provide increased virulence against fungi.

In each of the reviews completed thus far, the Agency determined that an EUP would be necessary to address unanswered questions about the effect of the organisms in the environment. A critical question to be answered in the EUP process relates to the ability of the organisms to replicate and spread beyond the application site. Though we believe the unanswered questions do not necessarily support the contention that these products may pose a high risk, we believe that it is prudent to now require additional testing in order to properly evaluate potential risks.

In reviewing small scale field testing notifications, EPA has developed an evaluation procedure designed to ensure that a thorough and accurate scientific assessment takes place. Internal review, which has been enhanced by bringing on board additional experts in the field of microbiology, is accompanied by review by other program offices within the Agency in order to achieve regulatory consistency, and by external peer review conducted under the auspices of OPP's legislatively mandated Scientific Advisory Panel (SAP). The SAP peer reviewers are selected based on their expertise on the issues involved to ensure that EPA receives the best possible feedback. Other Federal agencies, such as USDA and FDA, may also be consulted during the review if there is a potential jurisdictional problem or if another agency has particular expertise to contribute. Thus far, these procedures have served us well; however, we expect that they will evolve to accomodate additional experience with more sophisticated techniques.

Mr. Chairman, this concludes my prepared statement. I will be glad to answer any questions the Subcommittee may have.

Mr. Brown. Thank you, Mr. Schatzow.

Mr. Kendrick, would you like to proceed?

Mr. Kendrick. Thank you. Chairman Volkmer and Congressman Brown, we appreciate the opportunity to appear before this committee and discuss the U.S. Department of Agriculture's views on the potential impact of regulation of biotechnology research and development, and also to give you a brief summary of the public comments that we have received to date regarding the Department of Agriculture portion of the December 31, 1984, Federal Register notice that Dr. Healy has discussed.

Deputy Assistant Secretary Karen Darling of the Department's Marketing and Inspection Services has been a comember with Science and Education Assistant Secretary Orville Bentley to the Cabinet Council Working Group on Biotechnology and has represented the Department on regulatory aspects of biotechnology. She cannot be here today to testify, and thus I will attempt to represent the views of the Department.

As stated in the Federal Register notice:

> The manner in which regulations for biotechnology are implemented in the United States will have a direct impact on the competitiveness of the U.S. producers in both domestic and world markets and on the future development of the basic science.

The Department's regulatory philosophy regarding biotechnology is that agriculture and forestry products developed by modern biotechnology will not differ fundamentally from conventional products. We are much concerned with fully developing this new potential first and foremost for the Nation, its industry and its people broadly, but we are also cognizant of the benefits to all people of the world. We are equally and deeply concerned with continuing to develop and implement policies to help assure society's desired social and economic goals without untoward risks.

The challenge is to assure the public of adequate environmental safeguards without stifling the burgeoning growth of the new biotechnology industry and the attendant basic research and development processes.

In his testimony before this committee yesterday, Assistant Secretary Orville G. Bentley reminded members that USDA scientists were among the first participants in the meetings and discussions where DNA research policy was developed. The Department subsequently adopted the NIH guidelines for research involving recombinant DNA molecules and for coordinating interagency research review. Compliance with these guidelines is a condition for receiving funds for research.

We in the agricultural research community have long had much interest and experience with molecular genetics. Agriculture in this Nation today in the broadest sense, that is, the food, feed, and the fibering processes collectively, requires the use of genetically designed biologics—plant, animal, and microbial—on a sustained basis.

The agricultural community continuously assesses the impact of plants, animals and microbes within a wide range of cropping and animal production systems. These assessments are made not only to maintain agricultural stability, but also to assure the protection and preservation of the environment. Particular care is taken with the introductions of new plants, animals and microbes. Any new material is assessed carefully to determine if it is agriculturally beneficial without threatening the environment. For all major crops each State employs a wide range of protocols in which new forms, varieties, species and biocontrol agents are tested, recommended and appraised continuously for performance during commercial use.

At its founding, the Department was uniquely joined with the land-grant university development, and as a result the research and application responsibility is fulfilled through a system of State, Federal, and private cooperative efforts. We believe this vast network of scientific expertise, laboratories, and controlled environmental facilities have indeed provided good for the Nation in the past.

However, as I said earlier, we recognize and we accept the challenge of assuring the public of adequate environmental and health safeguards. As stated in the Federal Register notice of December 31, 1984, we believe that in agriculture—coupled with the proposal for a coordinated framework for regulation of biotechnology, and particularly with the operation of the scientific advisory mechanism within that framework—that we have sufficient authority under existing law to shepherd the new industry, safeguard the public interest, and permit the necessary research, development, testing and evaluation, production, and application of these biotechnology products, and to continue in an orderly—and permit them to continue in an orderly and timely fashion.

Regarding this assurance of adequate and responsible oversight, the Division of Agriculture Committee on Biotechnology of the National Association of State Universities and Land-Grant Colleges has recently issued an updated version of chapter 6, "Emerging Biotechnologies in Agriculture: Issues and Policies," Progress Report III, November 1984. I believe Assistant Secretary Bentley cited this document in his testimony yesterday and provided the committee with a copy. In chapter 6 of this document, the association proposes a national biological impact assessment program, or NBIAP. The primary function of NBIAP would be to study the effects of rDNA technology and to assess the possibility of risks to society and the environment. It is essentially a formalization of a system that has been in existence and effectively at work for many decades in the agricultural community.

The Association has designed the NBIAP to take advantage of the long history and successful experience of the State and Federal agricultural research systems. NBIAP would assess the biological impact of plants, animals and microbes produced by genetic engineering research including recombinant DNA—rDNA—methodologies. It would function in an open and a visible manner, and would assure that the maximum benefits of biotechnology research are gained for agriculture and society while again, continuously protecting the environment.

The Association proposes that NBIAP be established within the United States Department of Agriculture and its cooperating State institutions—the State Agricultural Experiment Stations and the State Cooperative Extension Service—in order to capture the benefits of existing experience in the most economic and efficient manner.

We believe the operation of the NIH RAC has proven the soundness and success of the advisory process. It is our concern at this juncture that not only are the needs and the concerns of the society, the biotechnology industry and the scientific community met, but that the massive new advantages of the Nation and the world are not lost. The Cabinet Council Working Group on Biotechnology plans to consider this proposal, the NBIAP, at their next meeting.

I would now briefly summarize the public comments that we have received to date regarding the Department of Agriculture portion of the Federal Register notice. Over 40 individuals have commented on the USDA proposal, either on their own behalf or on behalf of their associations or their companies. The comments are from individual research scientists, directors of research, presidents and vice presidents of biotechnology firms and chemical companies, presidents and executive directors of professional scientific associations, vice presidents for university research, university department heads, Members of Congress, and members of law firms and law journals.

While the comments of all these people and their organizations have not yet been thoroughly analyzed, since the period of comment did not end until April 15, a quick assessment finds strong support for USDA's proposed role in and approach to regulation and oversight of research, development, testing and evaluation, production, and application of biotechnology products for agriculture.

Also, there was a general feeling that USDA needs to more specifically outline their procedures as to how they will handle and review the approval of planned introductions into the environment and, perhaps, develop some interim procedures. Other comments suggested that USDA needs to address the confidentiality issue in dealing with industry submissions.

Mr. Chairman, this concludes my remarks, and I'll be pleased to answer questions as you desire.

[The prepared statement of Mr. Kendrick follows:]

Statement of

Edgar L. Kendrick

Administrator

Office of Grants and Program Systems

Science and Education

U.S. Department of Agriculture

Before the

Committee on Science and Technology

Subcommittee on Oversight and Investigations

U.S. House of Representatives

April 17, 1985

FOR RELEASE ONLY BY THE HOUSE
SCIENCE AND TECHNOLOGY COMMITTEE

Mr. Chairman, thank you for the opportunity to appear before this committee and (1) discuss the U.S. Department of Agriculture's views on the potential impact of regulation of biotechnology research and development; and (2) give you a brief summary of the public comments we have received to date regarding the Department of Agriculture portion of the December 31, 1984 Federal Register notice of a "Proposal for a Coordinated Framework for Regulation of Biotechnology." Deputy Assistant Secretary Karen Darling of the Department's Marketing and Inspection Services has been a co-member with Science and Education Assistant Secretary Orville Bentley of the Cabinet Council Working Group on Biotechnology and has represented the Department on the regulatory aspects of biotechnology. Since she cannot be here today to testify with me I will attempt to represent the views of the Department.

As stated in the Federal Register notice, "the manner in which regulations for biotechnology are implemented in the United States will have a direct impact on the competitiveness of U.S. producers in both domestic and world markets and the future development of basic science."

The Department's regulatory philosophy regarding biotechnology is that agriculture and forestry products developed by modern biotechnology will not differ fundamentally from conventional products. We are much concerned with fully developing this new potential first and foremost for the nation, its industry and its people broadly, but are also cognizant of the benefits to all people of the world. We are equally and deeply concerned with continuing to develop and implement policies to help assure society's desired social and economic goals without untoward risks. The challenge is to assure the public of adequate environmental safeguards without stifling the burgeoning growth of the new biotechnology industry and the attendant basic research and development processes.

To turn for a moment to recombinant DNA research, I want to note that USDA scientists were among the first participants in meetings, conferences and discussions where DNA research policy was developed. In 1976, a committee was formed in USDA to coordinate research policies both within the Department, and among USDA, the National Institutes of Health (NIH), and the National Science Foundation (NSF). This committee, authorized by the Secretary of Agriculture, is the Agriculture Recombinant DNA Research Committee (ARRC). In recognition of the need for uniform guidelines, the Department adopted the NIH Guidelines for Research Involving recombinant DNA Molecules for coordinating interagency research review. Compliance with these guidelines is a condition for receiving funds for research.

We in the agricultural research community have long had much interest and experience with molecular genetics. Agriculture in this nation today in the broadest sense, i.e., the food, feed, and fibering processes collectively, requires the use of genetically designed biologics -- plant, animal, and microbial, on a sustained basis.

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However, as I said earlier, we recognize and accept the challange of assuring the public of adequate environmental and health safeguards. As stated in the December 31, 1984, Federal Register notice, we believe that in agriculture coupled with the proposal for a coordinated framework for regulation of biotechnology and particularly with the operation of the scientific advisory mechanism within the framework, we have sufficient authority under existing law to shepherd the new industry, safeguard the public interest, and permit the necessary research, development, testing and evaluation, production and application of these biotechnology products to continue in an orderly and timely fashion.

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The Association has designed the NBIAP to take advantage of the long history and successful experience of the state and federal agricultural research systems. NBIAP would assess the biological impact of plants, animals and microbes produced by genetic engineering research including recombinant DNA (r-DNA) methodologies. It would function in an open and visible manner and would assure that the maximum benefits of biotechnological research are gained for agriculture and society while continuously protecting the environment.

The Association proposes that NBIAP be established within the United States Department of Agriculture (USDA) and its cooperating state institutions (State Agricultural Experiment Stations and the State Cooperative Extension Service) in order to capture the benefits of existing experience in the most economic and efficient manner.

We believe the operation of NIH/RAC has proven the soundness and success of the advisory process. It is our concern at this juncture that not only are the needs and concerns of society, the biotechnology industry, and the scientific community met, but that the massive new advantages to the Nation and the world are not lost. The Cabinet Council Working Group on Biotechnology plans to consider this proposal at their next meeting.

I will now briefly summarize the public comments we have received to date regarding the Department of Agriculture portion of the December 31, 1984 Federal Register notice. Over 40 individuals have commented on the USDA proposal, either on their own behalf, or on behalf of their associations or their companies. The comments are individual research scientists, directors of research, presidents and vice presidents of biotechnology firms and chemical companies, presidents and executive directors of professional scientific associations, vice-presidents for university research, university department heads, Members of Congress and members of law firms and law journals.

While the comments of all these people and their organizations have not yet been thoroughly analyzed since the period of comment did not end until April 15, 1985, a quick assessment finds strong support for USDA's proposed role in and approach to regulation and oversight of research, development, testing and evaluation, production and application of biotechnology products for agriculture. Also, there was a general feeling that USDA needs to more specifically outline the procedures as to how they will handle the review and approval of planned introductions into the environment -- perhaps develop interim procedures. Other comments suggested that USDA needs to address the confidentiality issue in dealing with industry submissions.

Mr. Chairman, this concludes my statement and I shall be pleased to answer any questions the committee might have.

Mr. Brown. Thank you very much, Mr. Kendrick.

Dr. Hardy, would you like to go next?

Mr. Hardy. Congressman Brown, Volkmer, and Packard, it is a pleasure to comment on the biotechnology area and its regulation. Let me introduce myself. I'm president of a start-up biotechnology company called BioTechnica International, located in Cambridge, MA. I also have one foot in academe as a visiting professor of life sciences at Cornell. I retired a year ago as director of life sciences at du Pont. And of possible relevance to this committee is that I chaired a national research council committee entitled "New Directions in Bioscience for Agriculture: High Reward Opportunities." That report was done for the ARS and issued within the last month.

Topics I'd like to address this afternoon are four in number. I'd like to put types of genetic engineering in perspective; to look at the track record that does exist in genetic engineering, to emphasize that there is, in fact, a track record out there already; to look at the impact of regulation; and finally, to make some general comments on recommendations for what one might view as an appropriate regulatory regime. Many of the comments that I will make are in more detail in a National Academy of Science publication issued recently. It's the publication "Issues in Science and Technology," and the article that I'm referring on is entitled "Our Investments: What is at Stake in the Biotechnology Area."

Genetic engineering can be divided into three types. One type is organismal, another type is cellular, another type is molecular. Organismal genetic engineering has been going on for decades and centuries. It's been practiced in agriculture and other areas in microbes, plants and animals. It involves selection, mutational sexual crosses, hybrids. It is a very random process. It requires a number of constructs to be made to select one that is desired. A large number of variants, in fact, have to be introduced into the environment by organismal genetic engineering.

And products are numerous in this area. There are seeds and animals, antibiotics, amino acids, microbial pesticides, *Rhizobia* for improved nitrogen fixation, cheese, spirits, bread, and so on.

Another type of genetic engineering is cellular. That's about 1 to 2 decades old. It involves either cell fusion or the culture of cells, and the regeneration of whole plants from those cells. This is a semi-random process in contrast to organismal genetic engineering, and the changes that are made are somewhat known in contrast to organismal where the changes, in general, are not known.

Products of the cellular area include monoclonal antibodies and there are crops such as sugar cane where cellular genetic engineering has been practiced for some time.

The third type of genetic engineering is molecular genetic engineering. This is about a decade old. It involves working at the molecular level, the DNA or the RNA level. It enables a directed control of the changes that are made. The genetic changes in this case, and in only this case of the ones I have listed so far, are, in general, known. And there are a relatively small number of variants that need to be made in this area to introduce into the environment because one knows specifically what one is adding or what one is deleting.

From these three types of genetic engineering, then—organismal, cellular and molecular—there is, in my view, a track record of organismal genetic engineering, from organismal genetic engineering. Novel organisms have been introduced into commerce and have been used in many ways, as I've listed already. And the organisms that we're talking about that will come from cellular and molecular genetic engineering will, in fact, be introduced and used in somewhat similar applications to those that have been used heretofore.

The examples that are the track record that I think are relevant to the considerations are microbial pesticides. As has been mentioned already at this hearing, 14 microbial pesticides have now been approved by EPA. This represents a period of 2 or 3 decades of approval, and they have been used in a variety of areas like agriculture and forestry, mosquito control, and so on.

Another very relevant area in the track record is rhizobiam. These are microbes that enable certain crops, legumes, to obtain their nitrogen freely from the atmosphere, and for almost all of this century rhizobiam have been introduced, deliberately released into our leguminous crops. Currently about 85 percent of the U.S. alfalfa crop is inoculated each year by rhizobiam that can be described as organismally genetically engineered. They have been selected or they have been mutated in one way or another prior to their introduction into the environment. About 50 percent of the 70-million-acre U.S. soybean crop is also treated with rhizobiam.

There is, in fact, a very substantial record on the ecology of the release of rhizobiam into the environment. I looked in a recent publication in the area of nitrogen fixation, and a chapter in that book addressed the ecology of rhizobia and there were 200 references in that particular chapter. And that indicates I think that there has been substantial work done and a substantial, if you will, track record or experience.

Other areas where there is a track record is the silage inoculant area where microbes are introduced broadly into silage in the farming practices.

From these and other examples, then, I suggest that there is a considerable experience with the use of genetically engineered organisms. That from these examples there is, in fact, no major negative health or environmental effects that have been identified. Furthermore, I would suggest that the absence of regulations documents society's perception of the relative safety of products that have come from organismal genetic engineering.

One can contrast that record, in fact, with the chemical area where in a few cases problems have occurred, and that has led to society creating regulation, such as TSCA, for these compounds. There is no reason, I think, based on scientific grounds, to expect that cellular and molecular genetic engineering will present any greater hazard than whole organismal genetic engineering has done. In fact, one can argue, since molecular genetic engineering allows you to identify specifically the changes that are being made, that it is possible to rationalize more effectively to predict more effectively what, in fact, will be the hazards out of molecular genetic engineering than out of the long practiced organismal genetic engineering.

What will be the impact of regulation? And this will depend upon, of course, the severity and the speed with which the process can move. It might, if it is slow and if it is excessive, certainly slow R&D in initial field trials, if one interprets the need for experimental use permits for the first field trials. Hopefully that will not be the case. However, as has been mentioned earlier today, that does not appear to be the view of EPA.

Regulation could substantially increase the cost of R&D throughout its whole process-to-product introduction. New nonproductive uses of the limited pool of outstanding scientific talent that is involved in the biotechnology area will be consumed, will take its time to pursue providing data for the regulatory route, can delay product introduction, and it can delay the benefits of these products to U.S. agriculture. And currently, at the moment, U.S. agriculture is in a most difficult situation, and products of biotechnology may enable decreasing costs of production in agriculture; and this I think can help to extract our agricultural system from its difficult situation.

In a broader sense, the United States could lose its competitive edge, as has been previously mentioned. U.S. companies in the extreme could move abroad if regulation becomes excessive. Delays in the prudent development or product development or costly regulatory clearances would be, I think, catastrophic for start-up companies. And having lived part of my life in a large established corporation, which tend to be cash rich organizations, and now living in an organization which is not cash rich, I have come to appreciate the importance of delays in terms of targets and the minimum amount of cash that's available in those organizations to allow them to continue.

I think it is also worth recognizing that studies have been done over the last few years that suggest that—that indicate that the rate of innovation in small companies, as opposed to large companies, is substantially higher. And I think that is one of the marvelous competitive advantages that the United States broadly has at the moment, is its number of start-up companies. And I think one has to be concerned that we don't provide an—that concerns so that we do provide an environment to enable those companies to move forward.

Some comments on general recommendations for appropriate regulations. The same regulation—let me skip here. The use of existing laws, as has been previously mentioned, I think is appropriate. I see no need for additional regulatory requirements for cellular and molecular over organismal genetic engineering. Why should one have to get an experimental use permit for the first field trials in a molecular genetically engineered organism as opposed to one that's been created by whole organism genetic engineering, when the end result may in fact be similar?

The current exemptions for R&D must be retained. R&D can be carried out as it goes into the field in small trials, and I think areas can be identified to isolate those trial areas significantly from major agricultural areas. A Government agency should have clear jurisdiction over discrete product areas. In the area of rhizobium, for example, it is not clear to me whether EPA or USDA, in fact, at this stage have the jurisdiction over that type of product.

There clearly needs to be a proper scientific capability. One would hope that we could use the available risk record, as I have mentioned, from whole organism genetic engineering. There is probably a need to sponsor research on risk assessment tools. Ecology is not a field that has been supported to the degree that other fields have been.

Since one is suggesting the regulation of an area for which there is no demonstrated health hazard or no demonstrated environmental problem, then the cost of this regulation I think clearly is a responsibility of society. I think if overly stringent regulations are introduced, both a major dollar and a talent investment that is being made in this country, and a major economic opportunity for U.S. industry, will be lost.

Thank you.

[The prepared statement of Mr. Hardy follows:]

PREPARED STATEMENT OF RALPH W. T. HARDY

Good afternoon. I am Ralph W. F. Hardy, President, BioTechnica International Inc., Cambridge, Massachusetts, Visiting Professor of Life Sciences, Cornell University, Ithaca, New York and Retired Director of Life Sciences, E.I. du Pont de Nemours & Company, Wilmington, Delaware. BioTechnica International is a development stage biotechnology company developing products for the agricultural, health care, food and beverage and energy industries. I also chaired the National Research Council Committee that produced the recently issued report, "New Directions in Bioscience for Agriculture: High Reward Opportunities" for the USDA's Agricultural Research Service. It is a pleasure to comment on the potential impact of federal regulation on the biotechnology industry.

My comments will list three types of genetic engineering ranging from whole organism to cellular and molecular, which differ only in process but not product. Organismal genetic engineering of microbes and plants has been practiced for decades. The deliberate release of such genetically engineered organisms as nitrogen-fixing microbes, microbial pesticides and improved seed has produced no significant negative environmental effect, but rather, has provided a major track record of the safety of genetically engineered organisms and the absence of a demonstrated need for regulation.

Regulation may produce a major negative impact on the world leadership position of the U.S. biotechnology industries, especially in the case of the highly innovative start-up companies. These negative impacts include major added costs and delays in product introduction, potential movement of industry to foreign countries, non-productive use of limited talent, and delays in the availability of the benefits of biotechnology products. General recommendations for an appropriate regulatory regime are outlined. Many of my comments have been presented in more detail in the Spring 1985 National Academy of Sciences publication, Issues in Science and Technology (Volume I, Number 3, pages 69-82).

The last two years have seen an increasing debate over the imminent use of genetically engineered microorganisms in the environment, and over how the federal government should regulate such use. This debate, which has broadened into a more general discussion of federal oversight over biotechnology products, was prompted in part by hearings by this subcommittee in June 1983. In the time since that hearing, a number of products have come closer to commercialization, including several modified organisms that are ready for small-scale field tests. In addition, a number of government agencies have begun developing possible regulatory approaches.

I will mostly discuss issues related to the environmental use of genetically engineered organisms. These will largely be products for use in agriculture, such as microbial pesticides, growth promotants such as Rhizobium, and, of course, modified varieties of crop plants, although there will also be non-agricultural uses of microorganisms in the environment (*e.g.*, organisms for waste treatment). Not only will genetically engineered agricultural products be used in the open environment, but these products and their prototypes must be field tested as an essential part of the research and development process. Therefore, the resolution of this ongoing debate will have great bearing on the successful introduction of new agricultural products that are expected to be of great benefit to the American farmer.

In discussing the development of "genetically engineered" agricultural products, it is important to stress that man has practiced genetic engineering in agriculture and other areas for centuries. The traditional breeding and selection of improved varieties of plants is a kind of genetic engineering where the genetic material of individual plants is combined to create new and useful traits. In this well-established form of genetic engineering, changes are made at the level of the whole organism. Using such genetic engineering methods, new plant varieties having novel genetic constitutions have been developed, field tested, and introduced commercially for many years. The same is true for agriculturally important microorganisms now commonly used in this country: the strains now used have been successfully developed by the genetic engineering techniques of mutation and selection.

Two new technologies have been developed in the past decade that enable genetic material to be modified at the cellular and molecular levels as well, thereby making possible a more deliberate and precise form of genetic engineering. It is these new cellular and molecular methods that offer the promise of vast benefits across a spectrum of industries, including agriculture.

I will distinguish between the three types of genetic engineering: whole organism, cellular, and molecular. In all three, genetic material is modified or combined to increase genetic variation, thus enlarging the pool of potentially useful traits. The three types differ not in the end product but in the process used to generate the genetic variability. In whole organism engineering, or traditional breeding, the process is largely random--that is, the entire sets of genes of two animals or plants are combined. The cellular and molecular technologies provide opportunities for unprecedented specificity, because smaller amounts of genetic information can be transferred than is possible in a traditional plant or animal cross. These new techniques make possible the addition or deletion of a single identified gene. Yet these new forms of genetic engineering are more technically challenging. In addition, although there is a large set of data by which to judge the impact of whole organism genetic engineering on human health and the environment, the volume of comparable data for cellular and molecular genetic engineering is small.

Whole Organism Genetic Engineering. Whole organism genetic engineering has been used for centuries to enhance the properties of plants, animals, and microorganisms for human use. Indeed, many current-day practices in agriculture and industrial fermentation are based on whole organism genetic engineering. Agricultural applications include the selection and breeding of animals and plants for improved quality, productivity, or disease resistance. They also include the selection and improvement of microoganisms for the inoculation of soils and feed.

In whole organism engineering, genetic variation is obtained or created by the collection of new genetic material from natural sources, by the repeated selection of organisms having desirable traits, by mutation, and by sexual crossing. Because these processes are random, they are hard to control. Thus, large numbers of variants must be produced to obtain a few containing the desired properties. This form of genetic engineering is labor-intensive and slow, especially for higher plants and animals. It is also restricted to species that are sexually compatible, and this limits the available gene pool. However, such sophisticated techniques as hybridization, artificial insemination, and embryo transfer have made whole organism engineering more effective.

Another limitation is that the specific genetic changes caused by whole organism engineering cannot be predicted or known. Thus, an animal or plant bred for a desirable trait may also have undesirable--and unrecognized--characteristics. For example, the cytoplasmic factor that facilitated the production of hybrid corn also made that crop plant susceptible to southern corn leaf blight, leading to an epidemic of this disease in North America in the early 1970s.

Cellular Genetic Engineering. Cellular genetic engineering uses the techniques of cell culture and cell fusion to create genetic variation. Many plant cells can be grown in culture, and some can now be regenerated to whole plants. For reasons that are still poorly understood, the process of culturing cells and regenerating plants releases a pool of genetic variation, known as clonal variation. In other words, many of the plants that are regenerated from culture are different from the parent plant from which they were derived. Thus, cell culture increases the supply of potentially valuable genetic diversity.

In protoplast fusion, cultured cells from different parents are fused in culture, giving rise to a hybrid containing the traits of both parents. Unlike production of hybrid plants by conventional methods, cell fusion allows genetic material to be transferred not only within but across species, thus overcoming sexual barriers.

Cellular genetic engineering is less random than engineering at the whole organism level. Thus, fewer variants need be created to produce an organism with the desired properties. In addition, selection of those plants having desirable properties is easier and less time-consuming at the cellular level than at the whole organism level. Nonetheless, cellular genetic engineering also has limitations. The specific genetic changes caused by the engineering may not be known, and other genetic changes may occur, as is the case in whole organism engineering. Cellular genetic engineering is moderately labor-intensive, although it requires less time per useful product than does whole organism engineering.

Cell culture is expected to have a major beneficial effect on agriculture. Some commercially valuable crops, such as sugarcane, can now be regenerated from cell culture, although this is not the case for other important crops, such as wheat, corn, and soybeans.

Molecular Genetic Engineering. Molecular genetic engineering uses recombinant DNA and related techniques to create novel genetic constructions. These molecular techniques make possible a directed, specific approach to genetic engineering. The specific gene or genes that carry instructions for a desired trait can be transferred from one organism to another. Thus, only a few variants are required to create an organism with desired properties, as opposed to the large amount required for whole organism engineering and the intermediate amount for cellular engineering. Moreover, only molecular genetic engineering provides the assurance of knowing exactly which genetic changes have occurred. These molecular techniques allow the rearrangement or amplification of genes within species, the use of synthetic novel genes, and the transfer of genes from one species to another. For these reasons, it appears that molecular genetic engineering will be far more effective than whole organism or cellular genetic engineering in creating variants of great utility. As with variants created through whole organism or cellular engineering techniques, the molecular genetic variants must also be evaluated to select those possessing the most useful properties.

The techniques of molecular genetic engineering will benefit agriculture in several ways. Agriculturally important microorganisms will be improved by recombinant DNA and other techniques, to create better pesticides, or to improve yields of certain crop plants. Plants themselves will also be modified by molecular techniques, by the development of specialized vectors designed to introduce new genetic information into plant cells. By the introduction of one or more novel genes, important crop plants may be made to grow faster, to have higher nutritive contents, or to be more resistant to disease or environmental conditions.

It is important to stress that, particularly in agriculture, novel organisms introduced into commerce will be used in very similar applications as currently-used organisms developed by whole organism engineering. As I have said, novel plant varieties, developed by classical breeding programs, have been introduced into the environment for many decades, and plants created by molecular engineering techniques can be expected to be introduced in similar ways. There are also numerous instances where whole organism-engineered microorganisms are used in agriculture today. Perhaps the most significant class is that of microbial pesticides. EPA has registered 14 microbial agents to date, and these are formulated into dozens of separate end-use products, having uses not only in agriculture, but also in forestry, mosquito control, and household pest control (F. Betz, Chemical Times & Trends, Jan. 1985, pp. 44-48). Experimental use permits have also been issued for limited field tests of several other whole organism engineered microbial agents.

Another significant introduction of microorganisms is the use of Rhizobium as an inoculant for legume crops. During most of this century, Rhizobium that have been improved through whole organism engineering have been used to inoculate millions of acres of agricultural soils in the United States. Approximately 85% of the U.S. alfalfa crop and 50% of the soybean crop are planted in the presence of a rhizobial inoculant, representing (by a conservative estimate) upwards of 10^{18} Rhizobium cells per year deliberately released into American soils. There are other agricultural microoganisms that have been used in the environment, such as silage inoculants.

Therefore, there is considerable experience with the use of genetically engineered microorganisms in the environment, in addition to the experience of classical plant breeding. There have been no major negative health or environmental effects that have resulted from this long practice of whole organism engineering in agriculture, and the absence of regulations documents society's view of the safety of products of organismal genetic engineering. This view is in contrast to the reality of the safety of chemical products where laws such as TSCA and FIFRA have been introduced to minimize environmental and health effects. Furthermore, there is no reason to believe that cellular and molecular genetic engineering should present any greater hazard than that posed by the whole organism genetic engineering that has been practiced for centuries. If anything, in light of the directed nature of the changes introduced into organisms through molecular genetic engineering, the possible adverse effects of modified organisms can be more reliably predicted than those associated with organisms mutated by traditional breeding.

The new technologies of cellular and molecular genetic engineering differ from whole organism engineering mainly in the methods used to produce the desired genetic variation, as well as in applications and knowledge about genetic changes. It would seem logical that the method of producing the genetic variation would be less important than the end product in terms of possible deleterious effects on human health or the environment. On that basis, the products of whole organism, cellular, and molecular engineering should be similarly regulated.

For a number of reasons, however, products of molecular genetic engineering, especially those intended for use in the environment, have drawn special attention. Increasingly, the public perceives that the risks posed by small-scale field tests of these organisms are real and that neither government nor industry is equipped to assess them. However, in most cases the new organisms are similar either to genetically engineered organisms already in commercial use or to naturally occurring organisms indigenous to habitats where they would be used. In these cases, experience with the wild-type or mutated organisms provides information with which to assess the potential risks of the new organisms. Indeed, the fact that similar organisms exist or have been previously introduced into the environment suggests that no adverse effects would occur from the introduction of a novel strain.

In addition, the techniques of molecular genetics also provide a method to monitor the distribution of the engineered genes in the environment. Pieces of DNA complementary to the introduced genes or to a signature sequence of DNA coupled to the introduced genes can now be used in the laboratory to probe for organisms carrying added DNA. In time it will be possible to use this DNA probe technology to facilitate monitoring in the field.

It is worth noting that the proposed regulation of the biotechnology industry is unique. If regulations are imposed, this would be to my knowledge the only case in which an industry has been made subject to significant health and safety controls before any hazards have been proved or any industrial accidents have occurred. Indeed, after nearly 10 years of close scrutiny, risk-assessment studies, and worldwide experience with molecular and cellular genetic manipulations, there is no evidence of any significant hazards associated with this technology--the risks remain only speculative. In fact, with the accumulation of knowledge, many of the fears voiced in the early days of molecular genetics have been shown to be unfounded.

In light of public concerns, I feel that some regulation of the environmental applications of genetic engineering may be necessary. Although no new laws or regulations are needed, the recent debate has illuminated areas in which existing regulatory authority may be exercised to apply to the products of the new genetic methodologies. Discussion has also centered on the need for better risk-assessment tools.

Industry desires a stable, realistic regulatory regime. Such a regime would allow companies developing products for release into the environment to incorporate the time and cost required to meet regulatory requirements into strategic planning. Unrealistic regulations that impede progress will not be well received by industry or the public, as this would certainly cause delays in the introduction of beneficial products. In general, excessive regulation may stifle innovation, and may lead to the non-productive use of this country's limited pool of outstanding scientific and engineering talent. Moreover, in the face of increasing international competition, the United States risks losing its competitive edge if the biotechnology industry is regulated too stringently, as this could lead to the movement of companies and technology to other countries. The start-up companies face an additional burden, since delays in product development or costly regulatory clearances could be catastrophic. This valuable U.S. resource could be severely damaged or lost if unrealistic regulations are established or regulatory agencies move slowly.

The following general recommendations could provide a basis for constructing an appropriate regulatory regime:

- Use existing laws. Products of cellular and molecular genetic engineering could be covered by existing laws. This approach would avoid the confusion of writing new laws for unknown risks.
- No additional regulatory requirements are necessary for cellular and molecular genetic engineering. There are no special risks inherent in the cellular and molecular genetic engineering technologies that compel additional requirements in the regulatory process. These processes should be seen as

alternative manufacturing methods, and risk analysis should focus on the end products rather than the processes. This is particularly true where considerable experience exists with the use of the parental organism in the environment.

- Current exemptions for research activities must be retained. Laboratory and greenhouse studies present minimal risks and should not be regulated. Small-scale exploratory field tests are also an integral part of the R & D process and are usually "contained" in the sense that they are conducted away from agriculturally important areas and under restricted access conditions. Thus, in contrast to large-scale commercial use, exploratory field tests should also be included under R & D exemptions.
- Government agencies should have clear jurisdiction over discrete product areas. Duplication of regulatory authority will lead to unnecessary disputes and delays.
- Proper scientific review. Risk-assessment studies must be based on case-by-case review by qualified scientists. Agencies should rely on outside consultants in the short term if this expertise is not available in-house, but they should quickly establish in-house capabilities.

- Use the available risk record from whole organism engineering. There has been considerable experience with the products of whole organism engineering in commerce and in the environment. This record should be considered in conducting risk-benefit analyses of the products of cellular and molecular genetic engineering.
- Research needs. Government agencies should conduct or sponsor further research to develop the information and the risk-assessment tools that are perceived to be needed.
- Society should directly bear the costs. Regulation proposed for genetic engineering is unique in that there are no proven hazards or industrial accidents related to the technology. Thus, there is every reason why society--not industry--should shoulder the burden of this regulation.

In sum, the safety record for whole organism genetic engineering indicates that little or no additional regulation is necessary for cellular and molecular engineering. In fact, the directed approach made possible by molecular genetic engineering is further evidence of its safety. Only in these new technologies is it possible to know and control the exact nature of the genetic change, unlike the more random processes used for years in breeding and selection. Moreover, it is becoming possible to fashion probes to monitor the fate of new genetic constructions, and biocides can be developed to recall novel organisms from the environment. Some regulation, however, appears to be inevitable. If overly stringent, both a major dollar and talent investment and an economic opportunity for the U.S. will be lost.

Mr. Brown. Thank you, Dr. Hardy.

Now, Mr. Doyle, can you help us overcome this technological optimism?

Mr. Doyle. Well, I have a few suggestions here that may be helpful. I have a prepared statement I will try to condense as I go along. And I also have a set of comments that I submitted to the Office of Science and Technology Policy on Monday, and I would ask that they be included in the record as well.

Mr. Brown. Without objection, it's so ordered. You waited till the last minute, just like it was a tax form, huh?

Mr. Doyle. Well, we had so much to say we had to work right up to the last minute.

I am with the Environmental Policy Institute, which is a nonprofit public interest research organization, and we also engage in litigation and public policy advocacy here in Washington and at the State and international levels as well. We work on a range of energy and natural resource issues. I am the one person at EPI that has dealt for the last 8 years with agricultural policy. For the last 3 years I have been working on a book about agricultural biotechnology, and in the course of researching this book I have visited with numerous scientists and businessmen. In fact, when Dr. Hardy was at Du Pont I paid him several visits to learn what Du Pont was doing in this area.

From the course of my research so far, there is no doubt in my mind that we have a revolutionary tool on our hands that poses much promise. But while there is much promise for both agriculture and the environment with this technology, there are also some clear reasons for concern and caution. How the Federal Government goes about regulating this technology, for example, may well determine whether biotechnology advances smoothly and safely or instead is hampered by conflicting jurisdictions and gray areas that invite public health or environmental calamity.

As I said, 2 days ago we submitted our comments to OSTP on their proposed regulatory framework. And at first glance this 51-page document in the Federal Register is a very impressive document with an elaborate matrix of proposed regulatory authorities. And we do commend Dr. Healy and her colleagues and the participating Federal agencies for coming this far in a relatively short time. However, we believe the document is, first of all, premature; and second, is inadequate and incomplete.

It is premature because the Federal Government is attempting to devise a regulatory framework before it has adequate scientific review capability in place, and this is especially true, we believe, in the area of deliberate release of genetically altered organisms into the environment. Second, the proposed framework is inadequate and incomplete for a number of reasons, including questions concerning legal authority, omissions of statement from key agencies, and lack of a clear public participation program—all of which we have outlined in the attached comments to the Office.

But, first here, I would like to consider some history connected with how this process evolved in the recent 9 months, particularly the history of the Federal Government's attempt to deal with the deliberate release issue. This is a history that we believe is punctuated by procedural mistakes. If you look at NIH's procedural blunder on their NEPA responsibilities, which led to litigation, then you have the on again/off again Federal agency initiatives such as EPA attempting to—before this subcommittee in 1983 claiming regulatory responsibility under FIFRA and TOSCA which was then delayed a year later by an OMB inquiry. The problem now as we see it is that you have agencies such as Commerce and the State Department pulling for our international position in biotechnology; you have agencies such as USDA whose historic mission is to emphasize the production, emphasize agricultural production and advocating more of the same with this new technology; FDA advancing the interests of the pharmaceutical industry; and you have a handful of people at EPA looking out for the public health and safety interests from an ecological standpoint. We see no agency that has the overall environmental and public health and safety as its main charge with this new technology.

And on top of this I think we are seeing now, on top of the OSTP, which we have just heard here at this table, almost monthly we have some new addition of proposed biotechnology program or a new assessment program. We've just heard USDA, today and yesterday, endorse a proposal for a national biological impact assessment program. Now, to my knowledge, that has not been included in the OSTP proposed framework. And with all of these various jurisdictions I think you have an increasing sense of confused responsibility in the Federal establishment, and I think for the average person it's confusing and almost defies description.

But I think the real core issue here, and I'd like to emphasize this in the remaining part of my testimony, is the science base. And here I would like to focus on the matter of making scientific predictions about what genetically altered microbes will or will not do in the environment.

Less than 2 years ago this subcommittee heard testimony from EPA, which then asserted it had authority to regulate certain products of biotechnology under FIFRA and TSCA. Yet, even then EPA's Administrator—Assistant Administrator, Don Clay, noted, and I quote: "There are almost no accepted methodologies for evaluating the safety of genetically engineered products." And Mr. Clay added then that the risk assessment tools and the data used for chemical substances could not apply in the case of living organisms. Clay then also explained that EPA needed to develop methodologies to evaluate environmental fate, human exposure and potential environmental and health hazards of such altered organisms. But he said that the tests were still several years away. How much closer are we to having that assessment capability today than we were 2 years ago?

Since Don Clay made these statements here 2 years ago there have been two other congressional hearings on the deliberate release issue. And independent scientists testifying at those hearings and other hearings and other scientists filing statements and affidavits in connection with litigation, all of this and all of these scientists have raised questions about the ability to predict what might happen in the environment with genetically altered organisms.

It is our belief that based on the scientific record and agency opinion so far that we have an uncertain situation with regard to adequately predicting what will happen ecologically with genetically altered organisms. We do need more information about risk and how risk assessment relates to regulation before we move ahead.

Now, usually when the Federal Government is faced with this kind of situation, it asks the National Academy of Sciences to conduct a study before taking action. The National Academy is the land's highest and most respected science body, and it is respected as a neutral arbiter and a sound and important source of scientific information. And indeed in this case the Academy, itself, saw the need for examination of the environmental and public health implications of genetic engineering last year, and they drafted a proposal to conduct a study on the health and environmental implications of genetic engineering. The Board on Agriculture and the basic—the Board on Biology have offered the proposal which is attached. I have a copy of the proposal attached to my OSTP proposal.

However, that study has run into difficulty obtaining funding since OSTP initiated its Cabinet Council Working Group in April, 1984, and its proposed framework just recently. In fact, sources I have contacted in the Academy have told me specifically that OSTP does not want the Academy to conduct this study because some people there do not want to broaden the public debate on the issue. Yet, in light of the incompleteness and inadequacy of the proposed OSTP framework and its political history, we believe that a comprehensive and objective study by the National Academy of Sciences on this subject is essential before the Federal Government or Congress move any further toward establishing biotechnology regulation.

Therefore, we ask this subcommittee, the full committee, and other appropriate committees in Congress to intercede at this time to ensure that existing NAS—that the existing Academy proposal is funded and undertaken immediately. The details concerning the Academy's original proposal, as I said, are included in our OSTP comments, and we have some suggestions for improving the scientific neutrality of that proposal and therefore put credibility and public confidence in any such study.

Mr. BROWN. Mr. Doyle, I'm going to have to interrupt you at this point. The committee, subcommittee will have to take a brief recess in order to vote on an important amendment, and we will return as quickly as possible and you may pick up your statement at the point on page 6 where you left off.

The subcommittee will recess for this vote and return as quickly as possible, and we will continue the hearing at that point.

[Recess.]

Mr. BROWN. Would you continue with your testimony, please?

Mr. DOYLE. Yes, Congressman Brown. Thank you.

As I left off, I had made the request that this committee and others throughout the Congress help ensure that we get the study from the National Academy of Sciences. Now, our purpose in making this request today is not to block the progress of this new technology, which we feel has some very promising potential for reducing pesticide use in agriculture, but to ensure that as a nation we take some time now to carefully evaluate where we are with our scientific capabilities before we begin approving thousands of products. It's not just the five that we see before EPA today; we're talking about thousands of products coming for thousands of locations that could be—have very lasting genetic changes that will be difficult, if not impossible, to recall if something goes wrong.

Now, if I could I would like to explore with you just one reason why we believe the predictive science base is so important. Today we have the capability of doing—what we have the capability of doing with biotechnology is artificially increasing the number of mutations in biological systems. And here I am borrowing heavily from the work of Dr. Martin Alexander of Cornell, a microbial ecologist who has testified before this subcommittee and has an article currently in the same issue that Dr. Hardy does.

In nature, the occurrence of a single mutation in a plant or a microbe is a relatively rare event, perhaps one in a million statistically. A second mutation arising from a successful population of the first mutant, called a double mutation, is even rarer, and perhaps unlikely in nature, put at a probability of perhaps one in a billion. But all that changes when science begins purposely selecting organisms for their mutations in the laboratory using high-speed techniques of biotechnology. What may have been a rare event in the natural environment with competing organisms and other biological pressures can in the laboratory become a predictable, controllable and repeatable occurrence. According to Dr. Alexander, double, triple and quadruple mutants can be made to appear, in his words, "with ease." Bioengineering, in other words, can increase the mutational frequency of organisms far beyond that of the natural environment, and such laboratory-bred mutants may express valuable characteristics, commercial and otherwise, that may never have been expressed in nature because of the odds against survival of new organisms generally.

Again according to Dr. Alexander, and I quote,

> We can create new genotypes which do have survival value even if the potential for the expression of that survival value would not ordinarily have occurred.

But what happens when such laboratory-based mutations are fashioned for use in the outside environment and released there? No one seems to know for sure. We simply don't have this predictive capability at hand. There has been little scientific study or data collection on how existing nonengineered organisms generally behave in nature let alone understanding of genetically altered ones. For example, little attention has been given to the dynamics of how organisms establish themselves, or why some species mutiply in nature and others do not, or what attributes make some organisms good at moving over large distances while others are poor at dissemination.

Some of this information does exist, as Dr. Hardy outlined for the—some of the literature on the ecology of *Rhizobia,* but not always for the organisms of most interest to genetic engineers or ways that were not—you know, not in ways that are useful in dealing with genetically altered organisms. The point is we do not have a good basis of scientific information that allows us to make reasonably sound predictions about what might happen. Unfortunately, we seem to have a history of discovering risk only after calamity or after substantial amounts of capital and production have been committed, after political positions have been taken and courses of action set in motion.

A second reason for our concern in the ecological as well as the economic area is how much we still do not know about the genetic realm; and here I, basically, listed some examples of our increasing knowledge about the genetic realm. And a few examples I listed were Barbara McClintock's work with jumping genes that dates to the 1950's, where they found that genes move from one chromosome strand to another, which at the time ran against conventional thinking and it took the scientific community more than 20 years to accept. In the early 1960's, we learned about plasmids, exchanging genetic material. That was a new piece of information. In 1970—the plant scientists discovered this—in our economy there was a devastating corn blight; 15 percent of the Nation's crop was wiped out. And the reason for that disease susceptibility was found in the cytoplasm. That was new information at the time. That was new genetic information just from classical plant breeding. I think that is an important example, and I think we should study those kinds of examples.

In 1983, we learned for the first time about the exchange of genetic material between chloroplasts and mitochondria. That was new information in 1983. Just a few months ago we've learned, or less than a few months ago we've learned of some variations in how paramecium and one kind of bacteria apparently send different kinds of protein codes; and that, again, is having an impact on the thinking about the genetic realm, the scientific information of the genetic realm.

I think with that, I have a prepared statement and it is in the record. I think with those examples I will stop here and just thank the subcommittee for allowing us to voice our concerns here today, and will answer any questions that I can.

Thank you.

[The prepared statement of Mr. Doyle follows:]

ENVIRONMENTAL POLICY INSTITUTE

TESTIMONY OF JACK DOYLE
DIRECTOR, AGRICULTURAL RESOURCES PROJECT
ENVIRONMENTAL POLICY INSTITUTE

BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT OF THE
U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON SCIENCE & TECHNOLOGY

THE REGULATION OF COMMERCIAL BIOTECHNOLOGY

17 APRIL 1985

Mr. Chairman, Members of the Subcommittee:

My name is Jack Doyle, I am Director of the Agricultural Resources Project for the Environmental Policy Institute (EPI). EPI is a non-profit, public interest organization engaged in research, public education, litigation and lobbying. Our researchers and lobbyists work on energy, environmental and natural resource policy at the local, national, and international levels. We appreciate the opportunity to appear before this subcommittee today to share our views on the very important topic of regulating biotechnology and the corollary issue of releasing genetically altered substances into the environment. We commend the chairman, members, and staff of this subcommittee for holding

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these exploratory hearings, and trust that they will be followed by others examing how these new biological and genetic technologies will affect our society, economy, and environment.

For the last three years, I have been working on a book about agricultural biotechnology, and in the course of researching this book, I have visited with numerous scientists and businessmen. There is no doubt in my mind that we have a revolutionary tool in our hands. While there is much promise for agriculture and the environment with the use of new genetic technologies, there are also some clear reasons for concern and caution. How the federal government goes about regulating this technology may well determine whether this industry advances smoothly and safely, or instead, is hampered by conflicting jurisdictions and gray areas that invite a public health or environmental calamity.

Two days ago we submitted our comments on the proposed OSTP regulatory framework for biotechnology. At first blush, this 51-page *Federal Register* notice is an impressive document, with an elaborate matrix of proposed regulatory authorities. And indeed, we commend Dr. ~~Bulkley~~, her colleagues, and the participating federal agencies for coming this far.

Yet, we believe this document is, first of all, premature, and secondly, is inadequate and incomplete. It is premature because the federal government is attempting to devise a regulatory framework *before* it has an adequate scientific review capability in place -- and this is especially true in the area of the deliberate release of genetically-altered organisms into the environment. Secondly, this proposed framework is inadequate and incomplete for a number of reasons -- including questions concerning legal authority, omissions of statements from key agencies, and lack of a clear public participation program -- all of which are outlined in the detailed comments we submitted to OSTP (and we ask that this document be printed in the hearing record).

But first, consider some recent history connected with biotechnology and genetics in this country; particularly the history of the federal establishment's fledgling attempt to come to grips with the deliberate release issue; a history punctuated by procedural mistakes such as NIH's procedural blunder on its NEPA responsibilities which led to litigation; and on-again, off-again federal agency initiatives, such as EPA's lone attempt in 1983 to claim regulatory responsibility under FIFRA and TSCA which was then halted by OMB a year later. The problem now, is that we have agencies such as Commerce and the State Department pulling for our international lead in biotechnology; agencies such as USDA emphasizing higher efficiencies and more agricultural production through biotechnology; FDA advancing products for the pharmaceutical industry; and virtually no one -- save a few souls at EPA -- looking out for the public health and safety.

Add to this the almost monthly addition of some new federal biotechnology program, and new assessment programs, such as

USDA's endorsement yesterday of a proposed National Biological Impact Assessment Program (which I don't believe was included in the OSTP framework), and you have an increasing sense of confused responsibility in the federal establishment that is bewildering and almost defies description. But the real core issue here is the science.

Consider the matter of making scientific predictions about what genetically-altered microbes will or will not do in the environment.

Less than two years ago, this subcommittee heard testimony from EPA, which then asserted it had authority to regulate certain products of biotechnology under FIFRA and TSCA. Yet, even then EPA's Assistant Administrator Don Clay noted, "There are almost no accepted methodologies for evaluating the safety of genetically-engineered products," adding that the risk assessment tools and data used for chemical substances could not apply in the case of living organisms. Clay explained that the EPA needed to develop methodologies to evaluate environmental fate, human exposure, and the potential environmental and health hazards of genetically-engineered organisms, but that such tests were "still several years away." How much closer are we today?

Since Don Clay made these statements, there have been two other congressional hearings on the deliberate release issue, and independent scientists testifying at those hearings, and others filing statements in connection with litigation, all of whom have raised questions about our ability to predict what might happen in the environment with genetically-altered organisms.

It is our belief, that based on the scientific record and agency opinions so far, that we have an uncertain situation with regard to adequately predicting what will happen ecologically with genetically-altered organisms once they are released into the environment. We need more information about risk, and how risk assessment relates to regulation, before we move ahead.

Usually, when the federal government is faced with this kind of situation, it asks the National Academy of Sciences to conduct a study before taking an action. And indeed, in this case, the Academy itself saw the need for an examination of the environmental and public health implications of genetic engineering last year, and drafted a proposal to conduct such a study. However that study has run into difficulty obtaining funding since OSTP initiated its Cabinet Council Working Group on Biotechnology in April 1984 and proposed its framework in December 1984. In fact, sources I have contacted in the Academy have told me specifically that OSTP does not want the Academy to conduct this study because some people there do not want to broaden the public debate on this issue. Yet in light of the incompleteness and inadequacy of the proposed OSTP framework, and its political history, we believe that a comprehensive and objective study by the National Academy of Sciences on this subject is essential before the federal government or Congress move any further toward establishing biotechnology regulation. Therefore, we ask this subcommittee, the full committee, and other appropriate committees in Congress to intercede at this time to insure that the existing NAS proposal is funded and undertaken immediately. The details concerning the Academy's original proposal are included in our OSTP comments as well as our suggestions for improving the scientific neutrality needed for credibility and public confidence in such a study.

Our purpose in making this request today is not to block the progress of this new technology -- which we fell has some very promising potential for reducing pesticide use in agriculture -- but to insure that as a nation we take some time now to carefully evaluate where we are with our scientific capabilities before we begin approving thousands of products for thousands of locations that could have very lasting genetic changes that will be difficult if not impossible to recall.

The recent history of scientists raising concerns about the potential ecological impacts and uncertainties of releasing genetically-altered organisms, plus the National Academy's own proposal which also discusses this issue, underscores the need for our nation's highest science body to study this matter comprehensively rather than leaving it fall to ad hoc White House working groups or individual agency initiatives.

Let me explore with you here just one reason why we believe the predictive science base -- a predictive ecology beyond what we have today -- is so important. Today, what we have the capability of doing with biotechnology is synthetically or artificially increasing the number of mutations in biological systems. And here I am borrowing heavily from the work of Dr. Martin Alexander of Cornell.

In nature, the occurrence of a single mutation in a plant or a microbe is a relatively rare event, perhaps one in a million statistically. A second mutation, arising from a successful population of the first mutant -- called a double mutation -- is even rarer, and perhaps unlikely in nature, put at a probability of one in a billion. But all that changes when science begins purposely selecting organisms for their mutations in the laboratory, using the high-speed techniques of biotechnology. What may have been a rare event in a natural environment with competing organisms and other biological pressures can in the laboratory become a predictable, controllable, and repeatable occurrence. According to Dr. Alexander, double, triple, and quadruple mutants can be made to appear with ease. Bio-engineering, in other words, can increase the mutational frequency of organisms far beyond that of the natural environment. And such laboratory-bred mutants may express valuable characteristics -- commercial or otherwise -- that may never have been expressed in nature because of the odds against the survival of new organisms. Again, according to Dr. Alexander, "we _can_ create new genotypes which _do_ have survival value even if the potential for the expression of that survival value would not ordinarily have occurred." But what happens when such laboratory-based mutations are fashioned for use in the outside environment and released there? No one seems to know for sure.

There has been little scientific study or data collection on how existing non-engineered organisms generally behave in nature, let alone understanding of genetically-altered ones. For example, little attention has been given to the dynamics of how organisms establish themselves, or why some species multiply in nature and others do not, or what attributes make some organisms good at moving over large distances while others are poor at dissemination.

Some of this information does exist, but not always for the organisms of most interest to genetic engineers, or not in ways that are useful when dealing with genetically-altered organisms. The point is, we do not have a good basis of scientific information that allows us to make reasonably sound predictions about what might happen.

Unfortunately, we seem to have a history of discovering risk only after a calamity, or after substantial amounts of capital and production plant have been committed; after political positions have been taken and courses of action set in motion.

A second reason for our concern in the ecological, as well as economic area, is how much we still do not know about the genetic realm. Consider, for example, some recent genetic history:

- In 1951, to the disbelief of her scientific peers, Nobel prize winner Barbara McClintock first offered her discovery of "jumping genes." McClintock discovered that the genes on chromosomes -- once believed to be stationary and therefore predictable in the genetic characteristics they controlled -- could move or "jump" from one chromosome strand to another, thus affecting changes in the expression of certain traits. What is most interesting and instructive about the McClintock episode is that it took nearly 20 years for the scientific community to finally accept her discovery.

- In the early 1960s, after several dysentery epidemics had broken out in Japan because some bacteria were beginning to become resistant to antibiotics such as streptomycin and tetracycline, scientists learned that tiny bits of DNA -- later known as plasmids -- which resided outside of the chromosome, could move freely among their own kind and even others of another species to communicate antibiotic resistant genes. That discovery caused a fundamental reevaluation of evolutionary theory, as well as the feeding of antibiotics to livestock on a routine basis.

- In 1970, plant scientists generally thought that the genetic traits that determine disease resistance and/or susceptibility in crops were contained in the nucleus of the cell. But after the Southern Corn Blight wiped out 15% of the nation's corn crop in 1970, they discovered otherwise. They discovered that cytoplasm -- the liquid material contained in every cell -- also had something to do with the genetics of disease reaction. That was new information.

- In 1983 we first began to hear the term "promiscuous DNA," meaning that DNA sequences could move about within the confines of the cell, in this case between chloroplasts and mitochondria. Scientists studying this transfer activity at Duke University and the Carnegie Institution concluded that this was not a rare event, but a "general phenomenon." Before this discovery, scientists had assumed that intra-cellular organelles like chloroplasts and mitochondria were independent of each other. Now they know differently, but how the DNA gets from one organelle to another is still a mystery.

- And only a few weeks ago was it revealed that researchers in the U.S., Japan and Europe studying *Paramecium* and one kind of bacterium, contain a DNA segment that sends a different protein code than what was standardly accepted as a universal truth, again changing the thinking about hard-and-fast rules concerning the genetic code as well as evolution.

Another concern of ours which relates directly to the question of the need for sound scientific information and regulation, is what the public is being told about this new technology. We hear much from the biotechnology industry and federal agencies such as USDA about how biotechnology is nothing new; about how it is only an extension of classical genetics. Yet while this technology can be described as an extension of the genetics of the past, it is a new dimension of genetic power; a power that can magnify in nature certain abilities that have taken thousands of years to evolve; a power that can now cross species barriers and design truly super breeds of plants, livestock and microbes. These are biologically-altered introductions of a new order that could well have super impacts of one kind or another -- of both the economic and ecological variety.

And on this point, it is interesting to note that the current debate over regulating biotechnology has focused almost exclusively on the potential environmental or ecological impacts. Yet an equally important reason for over-seeing the release of new genetically-altered products is the potential for substantial economic impact. The 1970-71 Corn Blight, which was the result of genetic alteration in the cytoplasm, caused a $1 billion loss. In my book, that's a very substantial economic impact. And I'm not sure we have learned the lesson of the Corn Blight yet.

I think we have a lot to learn from history, and in our OSTP comments we propose several in-depth case studies which evaluate our handling of crises such as the Corn Blight, the Med fly outbreaks, the rise of antibiotic resistance, Pennsylvania's poultry virus, and Florida's citrus canker. How have genetics played a role in each of these crises?

Today we read of a salmonella-in-milk production problem in the Midwest, a health problem now exacerbated by salmonella resistant to antibiotics. I think this is a vivid example of hwo mistakes and accidents can be magnified and compounded by what goes on in the genetic realm, and how we should approach that realm with care.

# # #

In the OSTP proposal, there is a great concern expressed for maintaining the U.S. lead in biotechnology; great concern for our "international competitiveness," as well as an eagerness for the "international harmonization" of biotechnology regulations. We hope, however, that the Reagan Administration's enthusiasm for the industry's international position does not result in our nation taking the lead for a lowest-common-denominator type regulation, which we believe would invite a "biotechnological Bhopal" that would surely damage the progress of this new industry as well as our credibility in the world community.

For these reasons, and others already mentioned, it is important that we pause now and have some rigorous scientific analysis of the biotechnology question, and particularly the release of genetically-altered organisms into the environment.

Thank you for allowing us to express our views here today.

ENVIRONMENTAL POLICY INSTITUTE

Comments of the Environmental Policy Institute
on
OSTP Proposal for a Coordinated Framework
for Regulation of Biotechnology
49 FR 5986

15 April 1985

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Comments of The Environmental Policy Institute
on
OSTP Proposal for a Coordinated Framework
for Regulation of Biotechnology
49 FR 5986
Date: 15 April 1985

Overview

The Environmental Policy Institute (EPI), a non-profit research and educational organization focusing on energy, environmental, and natural resource policy, wishes to commend the Office of Science and Technology Policy (OSTP), the participating federal agencies, and the Cabinet Council Working Group on Biotechnology for preparing the "Proposal for a Coordinated Framework for Regulation of Biotechnology," 49 FR 50856. The information contained in this proposal provides a useful first step in a long and necessary public debate on questions related to the potential social, economic and environmental impacts, as well as benefits, to come with this promising new technology.

On the whole, however, the OSTP proposal set forth in this Federal Register notice for regulating biotechnology raises more questions than it provides answers; is incomplete with respect to the role and concerns of other relevant federal agencies; assumes a level of scientific information and review capability that does not exist; and is generally premature for these reasons and others, particularly those having to do with containment and emergency procedures of genetically-altered organisms. Therefore, it is the conclusion of EPI that final action on this proposal should not occur until a whole host of questions raised here and elsewhere are thoroughly answered, and that at a minimum, a comprehensive and independent review of the biotechnology question, in all of its regulatory and environmental dimensions, be undertaken immediately by the National Academy of Sciences (see our recommendations and conclusion, pp. __).

Nevertheless, in the spirit of cooperation, and while not endorsing this or any other proposal for the regulation of commercial biotechnology until further scientific, congressional and public review of this issue occurs, we offer the following comments.

Legal Authority & Role of Congress

Although this proposal may serve as a useful collection of federal laws, rules, and agency statements covering existing legal authorities in a number of areas -- much of which has already been published elsewhere* -- we question its status as a legally-binding document or a legally-binding action by the federal government in the area of biotechnology regulation.

First of all, we ask where OSTP derives the legal authority for the publication of this proposed framework as well as the authority it expects to use to administer and enforce this framework in its final form? What is OSTP's legal authority for imposing this framework on other agencies and requiring them or the private sector to comply? If there are such authorities, they should be clearly set forth in the proposal. Moreover, if this is the precursor document for an expected Executive Order on this subject, then that should be set forth.

Moreover, one of the stated purposes of this OSTP notice and proposed framework is "to clarify the policies of the major regulatory agencies that will be involved in reviewing research and products of biotechnology." It is our understanding, however, that the judicial and legislative branches of the federal government are those vested primarily with the task of clarifying federal law and regulation, not the executive, particularly where amendment of existing statutes is needed.

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*See, for example, U.S. Congress, Office of Technology Assessment, Commercial Biotechnology: An International Analysis (January 1984), and Impacts of Applied Genetics: Micro-Organisms, Plants, and Animals (April 1981).

Moreover, since there is no clear or consistent set of definitions of terms such as "biotechnology," "genetic engineering," "hybridoma," "monoclonal antibodies," "protoplast fusion," and others (many of which are used in the proposal) found in any of the statutes cited in the matrix as possible legal authorities, it would appear that few if any of those laws could apply. And because of this it would also appear that the Congress, and not the Executive Branch, must determine the meaning of these terms and scope of their regulation before any clear authority or coordinated inter-agency framework could be put in place.* To do otherwise would be to invite definitional confusion and regulatory chaos.

Secondly, have those regulatory documents mentioned in this proposal purporting to amend agency procedures with regard to certain biotechnology products -- such as "points to consider" documents, memoranda of understanding, agency manuals, and other interim guidelines or discretionary authorities -- been scrutinized by the appropriate congressional committees for their overall effect and legal standing? What is OSTP's evaluation of these interim and ad hoc measures in terms of their coordinated impact on the proposed framework? Are these agency-by-agency "band aides" the best way to go about coordinating policy and regulating biotechnology, and do they have any binding legal effect on the private sector?

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*The very fact that a special glossary of terms, with more than 75 separate entries, is needed to accompany this Federal Register notice is ample indication of the newness of this technology, as well as the need for Congress to integrate those terms of art specifically into the appropriate federal laws.

Further, it would be useful for the Attorney General of the United States to render an opinion on the various authorities outlined in the matrix to determine if such authorities are compatible with one another, and how new legal problems peculiar to the nature of biotechnology might emerge in the context of this regulatory framework.

Coordination

Another of the stated purposes of this Federal Register notice is "to explain how the activities of the Federal agencies in biotechnology will be coordinated" (49 FR 50856). Yet, outside of the vague mention of an "interagency committee" to coordinate risk management and regulation in biotechnology (40 FR 50858), the notice never explains or provides specific examples -- even a hypothetical one -- of how such coordination might occur. For example, how should USDA review the current application of the Monsanto Company to EPA for a genetically-altered psuedomonas that is to serve as a microbial pesticide applied to corn seed? Should EPA and USDA review the product simultaneously, or should one agency logically review this kind of product before the other? And who will resolve any differences between the two agencies in their findings? A "walk through" example of this kind would be most instructive and helpful for citizens attempting to understand this framework.

Without concrete examples such as these, or more specific description of the procedures for implementing this proposal, the public cannot make a judgment about the scope or authority behind OSTP's proposed "coordinated framework." Certainly, OSTP is unwise and unrealistic if it assumes that the mere construct of a regulatory matrix alone is an adequate coordinating device. And although there are various memoranda of understanding between agencies cited in this proposal, they are not included in the notice for the public to examine in the context of whether and how they fit in the proposed framework.

Missing Information

Another major problem with this Federal Register notice is what is not said. Missing, for example, are statements of policy from other federal agencies that presumably might have an interest in, and/or jurisdiction over, any future regulation, permit or licensing mechanism, emergency containment actions, worker exposures, and other appropriate questions pertaining to commercial and research biotechnology.

For example, EPI believes that in addition to the statements of USDA, EPA and FDA, there should also be specific statements on the regulation of biotechnology from such agencies as: the National Institute for Occupational Health and Safety (NIOSH); the National Oceanic and Atmospheric Administration (NOAA); the U.S. Patent & Trademark Office (PTO); the Federal Emergency Management Agency (FEMA), and other appropriate emergency preparedness offices in EPA, USDA, DOE, and DOC. In addition to these, the statements of specific bureaus and divisions that may deal with biotechnology, or have some expertise on the subject should also be sought out. For example, in the Department of the Interior, agencies such as the U.S. Geologic Survey, U.S. Fish & Wildlife Service and the Bureau of Land Management; in the Department of Justice, the Land and Natural Resources Division; in the Department of Labor, the Office of Safety and Health and the Mine Safety & Health Adminsitration; and similar divisions or units within other federal agencies.

The point here is that biotechnology will clearly pervade all aspects of society from cleaning drains to enhanced oil recovery, and the federal government should first seek guidance from its own house of experts and regulators about how this technology will move and act in those various environments -- whether workplace, national forest or deep-mine shaft. Having extracted and compiled that basic information, the federal government could then uncover its informational, scientific, and regulatory shortcomings and _then_ publish a proposed regulatory scheme in the _Federal Register_ for public comment. In fact, without this kind of advance knowledge from those within the government, it is presumptuous and ill-advised for OSTP to prepare or propose a regulatory framework.

Parallel Federal Experiences, Specific Agency Actions & Case Studies

One way for OSTP and the relevant federal agencies to explore how they might adquately regulate biotechnology would be to compile and analyze parallel federal experiences with specific biological agents, recent disease organism outbreaks, instances of unanticipated events, and specific case studies focused on each of these areas. Several such case studies that come immediately to mind are: the 1970-71 corn blight, the Mediterranean fruit fly outbreaks in California, the Pennsylvania poultry virus, the Florida citrus canker, the rise of antibiotic-resistant bacteria due to the use of such antibiotics in livestock feed, and the recent salmonella-in-milk incident in the Midwest.

In addition, the records of individual agencies under specific biologic-type laws should also be analyzed. For example, it would be most instructive for the general public, Congress and the biotechnology industry to have a complete historical chronology and accounting of USDA, FDA, and EPA actions with regard to specific incidents under each of the laws mentioned in the Federal Register notice, how and why such actions were taken, descriptions of specific quarantines or containment actions, what their duration was, whether they were effective, how such actions affected interstate commerce and/or international trade, and whether such occurrence was repeated with the same or a mutated strain of pest or biologic agent.

It is also important for federal agencies dealing with licenses or permits for producing existing biological products to explain those functions clearly. USDA, for example, should identify for the public those companies and institutions that have received a U.S. Biological Products License under the Virus-Serum Toxin Act, as well as any companies which have had such licenses revoked or suspended by the USDA, indicating the specific incidents that led to such suspension or revocations. Moreover, how frequently are such licenses reviewed, and licensed operations inspected by USDA? Similar type information should also be sought out for the other appropriate federal agencies.

This kind of information would be very timely and useful in the context of the current question of regulating biotechnology. Unfortunately, it is not enough for an agency such as USDA to say that it has a broad range of experience in regulating plant pests, serums, and other biologic agents. The public needs to know if those experiences have been successful and will be relevant in dealing with the modern biotechnologies, their products, and/or their metabolites. Therefore, a detailed accounting of specific historical incidents, and agency decision making during those incidents, is necessary for the public to make informed judgments and comment about how those same laws and agencies might work or not work in a much broader area of public-health and environmental responsibility.

Environmental Risk & Lack of Predictive Science Base

Of the three federal agencies contributing policy statements to the *Federal Register* notice, EPA deserves special commendation for sharing with the public its thinking, analysis, and proposals for reviewing and regulating biotechnology products under FIFRA and TSCA. It is clear that the agency has not taken its responsibilities in this area lightly, and has done a credible job under difficult circumstances.

Yet there is a body of literature, scientific comment, and even a few EPA documents, as well as EPA and NSF officials on record, discussing the lack of a predictive ecology for microbial products, the difficulty of making scientific predictions about particular organism behavior generally, and other related "nuts & bolts" questions of EPA or some other agency gearing up to have a credible core biotechnology program in this new are of scientific prediction. But nowhere in the OSTP proposal, or the EPA section of this proposal, is the "predictive science" problem discussed for the general public. EPI believes that this issue is a major starting point from which all regulation in this area will begin, and for that reason, recommends that a detailed discussion and listing of what kinds of microbial and genetic phenomenon _can_ be predicted in the environment, as well as those which _cannot_ be predicted, be included in the framework proposal.

EPI also suggests that OSTP and all the federal agencies involved in the review and regulation of biotechnology should avoid using authoritative-sounding pronouncements about the safety, convenience, and cost of new biotechnological products. Rather, a more objective description of the potential benefits and risks of biotechnology should be used in all public documents. For example, in the second paragraph of the introduction of the _Federal Register_ notice, in discussing the "new services and a wide variety of products superior to those currently available" which biotechnology promises, it is noted that such products hold promise because "they _will_ be more effective, convenient, safer, or more economical" (emphasis added) (49 FR 50856). However, none of these descriptions and supposed qualities -- efficacy, convenience, economy or safety --

has been proven for all of the products of biotechnology, particularly since many of those products are unknown at this time. Therefore, such a pronouncement by OSTP is an opinion; it is not a statement based on fact, and should not appear in a Federal Register notice or any other government publication.

International Competitiveness

EPI also objects to the frequent references and discussions throughout the Federal Register notice devoted to the issue of how biotechnology regulation may impact the competitive position of the United States relative to other countries (pp. 50856-50857, OSTP; p. 50878, FDA; p. 50895, EPA; and p. 50904, USDA).

The tone of this discussion, as illustrated by the following paragraph excerpted from the first page of the notice -- which any conscientious citizen could not possibly avoid while beginning the arduous task of wading through this document -- is so forceful and brimming full of prideful nationalism that for one to think any other thought than that espoused might induce one to believe he or she is unpatriotic:

> The United States is now the world leader in biotechnology. This leadership is derived from a strong science base, a vigorous entrepreneurial spirit and availability of venture capital. New uses of biotechnology have created intense domestic and international competition. Several other nations have elevated the development of

> biotechnology to a national priority. The tremendous potential of biotechnology to contribute to the nation's economy in the near term, and to fulfill society's needs and alleviate its problems in the longer term, makes it imperative that progress in biotechnology be encouraged (emphasis added). 49 FR 50856.

Moreover, this concern for biotechnology's progress, as stated by OSTP in the opening section, goes beyond our own national borders, as the reader is made aware that "attention will be paid to international harmonization" in a range of regulatory and technical areas, and that the U.S. is also "committed to reducing barriers to trade in biotechnology." Indeed, OSTP's enthusiasm can hardly be contained:

> Barriers to trade of biotechnology products can only be avoided if the U.S. and other nations join together in working toward this goal (i.e., similar treatment of products and approval procedures among nations). In achieving national consistency and international harmonization, regulatory decisions can be made in a socially responsible manner, protecting human health and the environment, allowing U.S. producers to remain competitive and, most importantly, assuring that everyone will reap the benefits of this exciting biological revolution. 49 FR 50857.

In their respective sections, FDA, EPA, and USDA also raise the potential impact of regulation on the U.S. competitive position and the need for "international harmonization." Only EPA, however, mentions the topic of international environmental risks, but without elaboration (49 FR 50895). And while much is made of the international competitiveness issue and regulatory harmonization throughout the notice, there is no statement on either of these or related questions from either the Department of Commerce or the U.S. Trade Representative's Office.

EPI expects that OSTP and other federal agencies should treat the subject of international competitiveness with more balance.* Moreover, in its enthusiasm for keeping our technological lead and the commercialization of biotechnology moving ahead, the federal government should not also take the lead in creating a "lowest-common-denominator" international regulatory regime that invites a biotechnological Bhopal, which will surely thwart the biotechnology industry's progress and damage U.S. credibility in the world community.

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*In the OTA study cited by OSTP at 49 CFR 50857, for example, much is made of the potential for Japan to become a strong competitor in biotechnology. Yet on the subject of Japan's supposed ascendancy in biotechnology, the public should also be aware of a somewhat different view, such as that of Gary R. Saxonhouse, Professor of Economics of the University of Michigan, who has visited Japan and written widely on the Japanese biotechnology industry) See for example, Gary R. Saxonhouse, "The Japanese Biotechnology Industry," address delivered at the Symposium on Biotechnology, Creating an Environment for Technological Growth, National Academy of Sciences, Washington, DC, February 27-28, 1985.

AID-Funded Research in Foreign Countries

Another area of concern, and one that is not covered in the OSTP proposal, is that of biotechnological research projects in foreign countries funded by federal agencies such as U.S. Agency For International Development (AID). Some of these projects may be nearing the field-test stage, and some may involve genetically-altered microbial products with toxin genes for killing insects and other microbes. Yet there is no specific entry for AID or any law covering this kind of activity in the matrix.

And beyond the question of AID's regulatory jurisdiction in biotechnology and dealing with the potential environmental impact of this kind of research activity, is the question of the liability of the United States government should such an experiment go awry. Moreover, even assuming there is no potential ecological problem with a given field test in a foreign land, there are still questions of equitable treatment and equitable regulation, so that U.S.-funded experiments abroad are conducted under the same rules as those conducted in universities and companies in the United States.

Microbial Factories & Crop Vulnerability

Biotechnology and genetic engineering will dramatically change the way a wide array of industries secure and manufacture certain raw materials and industrial intermediaries -- from energy resources and industrial oils to chemicals, drugs and ingredients used in food processing. Microorganisms -- yeast, fungi, bacteria and viruses -- have varying properties and qualities that are valuable to industry for one or more purposes. Yeasts and bacteria, for example, have long been used in cheese- and beer-making. Yet today, with biotechnology, and the potential lower cost of using multiplying microbes in large-scale facilities to produce a variety of substances, microbial fermentation with gene-specified products is attracting renewed interest. However, some of the microbes presently in use -- as well as unknown numbers of microbes being planned for use in biotechnology -- are pathogenic to some platn species and agricultural crops.

For example, xanthan gum* is an industrial product made by a species of bacteria named Xanthomonas campestris. However, this particular strain of Xanthomonas, as well as 7 other strains, can cause disease in crop plants, such as leaf spot in alfalfa, common blight of beans, and black arm of cotton. Tomatoes, peppers, sugar cane, walnut trees and rice are also susceptible to certain strains of Xanthomonas. In recent years in the U.S. for example, pathogenic strains of Xanthomonas campestris have caused over $1 million worth of damage to certain vegetable crops.

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*Xanthan gum is an ingredient used in the making of ice cream, cheese spreads, clear-gel toothpastes, and other foods and consumer products. Xanthan gum also has uses in printing inks, paints, abrasives, adhesives, ceramics, cleaning agents, explosives, and agricultural products such as sprays and feeds. In the future, Xanthan gum may also be used for enhanced oil recovery. Because of its "pseudoplastic properties," it is already a key ingredient in drilling muds.

The obvious question of course -- and one which OSTP and the appropriate federal agencies need to address -- is to what extent biotechnology's use of microbes such as Xanthomonas campestris -- and thousands of others like it with potential to produce a wide range of substances for commerce -- pose a danger to agricultural crops. Should such species accidentally escape from a modern bio-process factory -- particularly given the huge stands of genetically-uniform and vulnerable crops in modern systems -- they could cause crop epidemics of enormous proportions, even hundreds of miles away from the site of their accidental release.

In the various stages of culture preparation, microbial growth, fermentation, and subsequent phases of processing microbes, aerosols of the microorganisms used are generated, and if adequate precautions are not taken, these aerosols can be released into the environment. In fact, three British scientists investigating microbial production processes for the EEC had strong reservations about the safety of handling plant pathogens in large-scale operations.

"Provided the scale of manufacture does not exceed a few thousand litres," they wrote in their 1981 report,* "containment of the aerosols generated at all stages is possible. As the scale increases so the cost of and the difficulty of containment inevitably increases. We do not, therefore, believe that a plant pathogen, which is still fully virulent after growth in a fermenter, can, at present, be handled safely on a very large scale; at least, in the vicinity of crops of suitable host plants."

Needless to say, with commercial biotechnology of this fermentation variety on the near horizon, this is an "environmental release" issue that should be of some concern to the federal government, yet there is no mention of it in the proposed OSTP framework.

Status of FDA's "Plant Breeding" Regulation

Under Section I of the matrix, with regard to the Food, Drug and Cosmetic Act and its regulations, 21 CFR 121 is not mentioned. In this regard, your attention is specifically addressed to 21 CFR 121.3(b)(2)(ii), a 1971 GRAS regulation having to do with substances (particularly new crop varieties) that have had significant alteration of composition by breeding or selection, the change in which may reasonably be expected to alter to a significant degree either the naturally-occurring nutritive content or the concentration of toxic constituents. According to correspondance between EPI and FDA on this question (see appendix __), this regulation, which specifically applies to new crop varieties, and may also apply to livestock, is still current, but no guidelines for this particular regulation have ever been published.

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*See C.G.T. Evans, T.F. Preece and K. Sargeant, "Microbial Plant Pathogens: Natural Spread, and Possible Risks In Their Industrial Use," a study of the necessity, content and management principles of a possible Community Action, Commission of the European Communities, XII/1059/81-EN., 74 pp.

Under the proposed framework, to what extent will this FDA regulation apply to agricultural crops and livestock genetically-altered through biotechnology techniques? Moreover, it would be useful to conduct an inquiry into FDA's experience with this regulation because it involves classical genetic alteration and may provide some valuable insight for reviewing new crop varieties altered through recombinant DNA techniques or other biotechnology methods. Further, OSTP should address how this regulation relates to USDA actions in the crop breeding and livestock area now, and how this may change, if at all, with biotechnology products?

Scientific Advisory Mechanism & Public Participation

EPI agrees wholeheartedly with OSTP's statement that "regulatory decisions must be solidly based on the best available science." But OSTP should add, that in terms of biotechnology, and in particular, the needed science base for risk assessments associated with this technology, such science barely exists, and is unavailable, and what is available is only "second best." For this reason, OSTP should conduct an agency-by-agency review of the existing scientific capability in the federal government before it finalizes any proposal for a scientific advisory mechanism for biotechnology, and that such inventory, along with a few in-depth case studies of how existing scientific advisory review boards and committees have worked, should be made available to Congress and the general public for review and comment.

A related and very fundamental question in our view is the need for neutral scientists -- those not affiliated or connected with biotechnology firms either as employees or as investors -- to serve on federal advisory and/or consulting boards for biotechnology reviews. In the OSTP proposal for a Biotechnology Science Board and the accompanying agency-based scientific advisory committee, there is no discussion of prior or existing affiliation of the scientists, what disciplines should be represented, or how long selected scientific advisors should serve. We believe that all such boards should be exclusively comprised of independent scientists who have no connection with, or financial interests in, companies that will be producing biotechnology products.

Further, there is no mention of the public's role in reviewing these decisions or to what extent such proceedings would operate in public view. EPI believes it would be important to have the general public and non-scientific interests represented on these boards, if for no other purpose than simple observation, even where proprietary information is involved. Further, all such meetings of these advisory boards should be open to the public.

Review by Broader Public

In all probability, due to the arcane nature of this subject, and the general obscurity and density of *Federal Register* notices, this particular proposal for a coordinated regulatory framework will likely receive more attention from academic scientists engaged in this work, as well as commercial and governmental interests with a direct stake in policy and product futures, than it will from average citizens, farm organizations, and state officials. For this reason, it will be particularly important that OSTP publish a complete listing of those individuals and organizations responding to this notice, *before* any final publication is contemplated. Moreover, at a bare minimum, a public hearing -- and preferably, a series of field hearings -- should be held.

Confidential Business Information (CBI)

Corporations and biotechnology companies have a right to protect proprietary business information in the regulatory process, and EPA and other agencies abide by such "CBI" provisions set forth in federal regulations. These CBI procedures have been reiterated in the OSTP Federal Register notice with regard to biotechnology products and the proposed regulatory framework. Yet, a recent incident at EPA involving a CBI claim by the chemical company Monsanto on a letter from EPA outlining steps the company should take in connection with a microbial pesticide application, raises disturbing questions about how these provisions may be used inappropriately, and in ways which deny the public access to regulatory information and decision-making.

EPA officials had stated publicly on March 28th, 1985, that an agency letter prepared for the Monsanto Company was available to the public (but the attachments were not). The letter's content instructed the company what steps it could take to reduce risk and bring its application for field testing a genetically-altered microbial pesticide closer to final approval. In the interim, the Monsanto Company has blocked the release of the letter to the public, claiming it is confidential business information. Yet some agency officials believe the letter's content is regulatory in nature, and does not contain confidential business information.

If this is true, the public may be unduly being denied access to viewing the regulatory process; a process that has historically been open to the public, and certainly in this instance of a totally new technology being regulated with interim measures, should not be removed from the public eye. Moreover, if the Monsanto Company has proprietary designs on the steps outlined in EPA's letter, that raises a whole new area of potential controversy as well as questions of appropriateness. OSTP, however, should clearly set forth how it believes CBI provisions will apply to biotechnology products and processes given this recent claim by the Monsanto Company.

Research Priorities, Alternatives, NEPA & Regulation

In many ways, this OSTP proposal is a reactive document rather than a leadership document. There is no consideration, for example, of broader social and environmental questions concerning which applications of biotechnology should be pursued first; no discussion of research priorities from the federal government's point of view.

Should not the White House Office of Science & Technology Policy -- the President's science office -- make some specific recommendations of what particular directions it thinks biotechnology should be moving? For example, if corn can be genetically engineered, or even cross-bred using existing classical techniques, to genetically resist black cutworms, how does that compare economically and environmentally with a genetically-engineered microbial product designed to kill black cutworms? Which is less risky for society and the environment? Which is less costly?

These kinds of questions do not appear to have been addressed by the federal government in the preparation of this proposal, yet to our thinking, they do bear directly on questions of risk and regulation.

In this regard, some discussion of the National Environmental Policy Act's provision for consideration of alternatives to proposed federal actions would to be useful in considering biotechnology's range of offerings. And on this point -- particularly with regard to weighing alternatives when reviewing specific federal actions -- it would be important to consider why EPA should be exempt from NEPA. Might this exemption now preclude EPA from looking at alternatives as part of its emerging regulatory responsibilities in the biotechnology area?

Cabinet Council Involvement & Political History

One of the reasons why this OSTP attempt at interagency coordination fails to convey a consistent and well thought-out approach, we believe, has to do with political motivation of the Reagan Administration and the recent history of the deliberate-release debate. The sequence of events between August 1983 and May 1984 -- including 1) EPA's assertion that it would regulate genetically-engineered products under FIFRA and TSCA (August 9, 1983); 2) litigation begun against the NIH for improperly approving federally-funded field experiments with genetically-altered microbes (September 1983); 3) the publication of the House Science and Technology Subcommittee staff report "Environmental Implications of Genetic Engineering" (February 1984); 4) U.S. State Department concern over the competitive international position of American biotechnology companies; and 5) an OMB proposal to take the lead on the regulatory question (March 1984) -- have all figured prominantly in moving EPA out of an emergent regulatory position, and moving the White House into control of the issue through OMB and OSTP.* Politically, this centralization of the inter-departmental squabbling over biotechnology under one roof gave the outward appearance of some working order, and had the effect of out-flanking Congressional interest for the time being. Moreover, the resulting *Federal*

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*In fact, some of the history behind the present OSTP effort dates to an October 1982 inquiry on U.S. biotechnology competitiveness commissioned by George Keyworth, then OSTP Director and Science Advisor to the President. That effort was organized as a working group headed by William J. Walsh of the State Department. In April 1983, a smaller group of individuals involved with this study met with nine key representatives of biotechnology companies and major corporations at a Virginia

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*(footnote continued) retreat for two days to finalize the report's recommendations. Walsh described that draft -- which was submitted to OSTP on May 27, 1983 -- as "a data base with suggestions on how government agencies should change their ways in such areas as patents, licenses, export controls, and FDA regulation so as not to lend themselves to selling out state-of-the-art cheaply, and to unshackle industry in pursuit of biotechnology." The report recommended, for example, removing certain disincentives to biotechnology in the tax, patent and anti-trust area. "The current situation," wrote William Walsh in his letter to Keyworth transmitting the study, "does not warrant more restrictive control measures, which could be counter-productive."

Subsequently, on a separate track, OMB became involved in the issue. In early 1984, after EPA had circulated a draft biotechnology regulation for publication in the *Federal Register* with regard to its perceived responsibilities under FIFRA and TSCA, Christopher DeMuth, an OMB official, objected. In a March 12th, 1984 memo to the Cabinet Council on Economic Afairs, DeMuth argued that the Council should decide how to regulate biotechnology, not EPA. In the memo, DeMuth referred to EPA's proposal as a "gambit," and voiced concerns that too much regulation would hurt biotechnology companies which he viewed then as "extraordinarily innovative" but "unusually sensitive to regulatory costs and delays." He also outlined several options including: doing nothing, asking the National Academy of Sciences to study the issue, and keeping the status quo in tact under NIH, among others. One report charged that OMB and DeMuth were under pressure from the Department of Commerce and Commerce Secretary Malcolm Baldridge, who was concerned that EPA regulation would hinder U.S. biotechnology companies in competition with Japan. All of this internal politicking led to demise of EPA's and William Ruckelshaus' lead on the biotechnology question. By April 30, 1984, the Working Group on Biotechnology of the Cabinet Council on Natural Resources had been created, under the chairmanship of OSTP's George Keyworth. It is that working group which formulated -- in a period of 9 months' time -- the current *Federal Register* notice and regulatory matrix.

Register notice has kept everyone busy making comments. Yet the political history surrounding this notice underscores, and is responsible for, its inadequacy, its unevenness, and its lack of scientific thoroughness. And now even the future of the Cabinet Council working group on biotechnology is in question with the recent White House announcement of Cabinet Council consolidation.

But the real issue here is the lack of scientific information on the effect of releasing genetically-altered microbes into the environment, and for that, there is no remedy offered by this federal notice.

Proposed Study by the National Academy of Sciences

On May 17, 1984, the National Academy of Sciences' (NAS) board on Basic Biology, and its Board on Agriculture jointly issued a proposal entitled, "Environmental and Public Health Implications of Genetic Engineering,"* which proposed a study "of the biological, ecological, and agronomic principles governing the fate of genetically-altered organisms and other products released in the environment."

The Academy's proposal notes:

> There is a pressing need for better understanding of such scientific principles and criteria among federal agencies currently exercising oversight, research, and regulatory

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*the full text of that proposal is included in Appendix B.

> responsibilities in this area.... To assure that scientific and regulatory resources are properly focused, it is important to differentiate genetically engineered commercial products posing new and unique risks from those products that are unique only, or largely because genetic engineering techniques were used in their development or manufacture.

Moreover, among the study's expressed purposes were to "facilitate progress toward a consensus of judgment of the scientific community on implications of the release of genetically engineered organisms" and to "provide useful information and guidance for research and regulatory agencies."

Thus, this NAS document found that there is no "consensus of judgment" among the scientific community about the implications of releasing genetically engineered organisms into the environment, and that there is a lack of scientific information on which to predicate sound regulatory action. Yet, with the current Federal Register notice and proposal, OSTP and at least 3 other federal agencies presume that such information exists.

Further, the NAS proposal reiterated this "lack-of-scientific-principles" theme in its summary, while discussing the need to protect the public:

> In order to more fully realize the potential commercial and social benefits of genetically engineered microorganisms, plants, and other products, appropriate steps need to be taken to protect the public from unforeseen hazard. To do so, a close understanding is needed of the environmental and public health implications thought to be associated with different types of

> organisms and products. The purpose of this study is to analyze the basic scientific questions that must be resolved, at least in a preliminary fashion, in order to realistically structure responses to concerns regarding their safety and environmental fate. Such an appraisal is both needed and timely to support the development of sound public policies pertaining to research and development, licensing provisions, regulatory requirements, and a research agenda for risk assessments, as appropriate.

Even though the background section accompanying this NAS document notes that the proposed study "addresses a very significant and pressing problem," that funding prospects for the proposal were "excellent," and that Dr. Orville Bentley of USDA had "indicated on numerous occasions that USDA would be supportive of such a project," this NAS study has not yet been funded. Moreover, some officials at the Academy indicate that there has been "resistance" from some federal agencies to the initiation of this study.

Conclusion and Recommendatiosn

While OSTP and the three participating agencies have, for the most part, provided a public service in assembling a wide range of information on the possible legal authorities for regulating biotechnology, as well as in providing the public with some of their initial thinking about how to regulate this new technology from the standpoint of public health and safety and environmental protection, EPI believes that this proposed framework is premature for several reasons. We conclude that this framework not be formally adopted until two critically important pre-requisites are met.

First, the proposed National Academy of Sciences study, "Environmental and Public Health Implications of Genetic Engineering," should be funded and completed in advance of any federal agency or Congressional action to adopt a regulatory framework for biotechnology generally, or before any federal agencies approve specific products or proposed field tests of genetically-altered organisms. The range of federal agencies funding and reviewing the NAS study should include those mentioned in the Academy's proposal -- EPA, NIH, NSF, USDA, DOE, and DOD -- but should also include the participation of OSHA, AID, FEMA, the Department of Commerce, and the Office of U.S. Trade Representatives.

Further, the Academy boards actually participating in the research, writing and analysis of the study should include members who are scientists and officials in government service or those holding academic or scientific association positions, and who have not been affiliated with commercial biotechnology firms during the last two years, or who currently hold any financial interests in a biotechnology company or hold a patent on a biotechnology product or process. Such precautions are necessary to insure the credibility and objectivity of the study's conclusions and recommendations. However, we do not suggest that the Academy must avoid the opinions and information of companies and corporations engaged in biotechnology. On the contrary, such information will be important, and is in fact crucial, to the Academy's review of the field. Yet such information can be collected through workshops with industry representatives -- as well as those representing other interests and the general public. If the Academy's findings in this area are to be accepted by the general public and policy-makers as the informed view of the nation's top scientific authority, then there should be absolutely no questions of conflict of interest or improper influence that could color the study's veracity and its objectivity.

Secondly, once this study is completed by the Academy, the final document should then become the vehicle for comprehensive congressional and public review. In Congress, the appropriate committees dealing with biotechnology products and processes, as well as the public health and environmental implications of commercializing this technology, should weigh and review the Academy's report for its legislative ramifications.

In addition to Congressional hearings held in connection with the review of the Academy's study, the Academy itself and/or OSTP might consider conducting its own set of field hearings around the country to solicit public comment on the study and the issues of public health and safety and environmental protection.

Only after these steps have been taken should the appropriate federal agencies and the appropriate congressional committees move to consider specific regulatory proposals. The risks at this point are too unknown, the scientific base too inadequate, and the legal authorities too unclear for the federal government to take other than the most prudent course of careful study before it embarks in regulating one of the most far-reaching technologies ever to confront society. Hastily conceived regulatory frameworks and legal precedents could haunt our society for years to come, not to mention slow technological progress should these spawn an industrial accident or the wrong kind of federal activity.

APPENDIX A

Exchange of Letters Between
EPI & FDA

ENVIRONMENTAL POLICY INSTITUTE

2 May 1984

Dr. Mark Novitch
Acting Commissioner
U.S. Food & Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Novitch:

In the June 25, 1971 edition of the Federal Register (pp. 12093-12094), FDA published rules and regulations pertaining to those substances "generally recognized as safe in food", called the GRAS list.

Section 121.3 (b)(2)(ii) of those regulations included as eligible for FDA review: "substances that have had significant alteration of composition by breeding or selection and the change may reasonably be expected to alter to a significant degree the nutritive value or the concentration of toxic constituents therein".

As director of the Environmental Policy Institute's Agricultural Resources Project, and currently working in the area of agricultural biotechnology and agricultural genetics, I have a few questions about this regulation and FDA's current involvement with it. Specifically, my questions pertain to the development, present status, and future applicability of this GRAS regulation, and I would appreciate a response from your agency to the following:

1) Are there FDA reports and documents pertaining to the basis for and history of this regulation, including minutes of meetings with other federal agencies, industry representatives and consumer interests? Can this information be made available to the Environmental Policy Institute?

2) Is this regulation curently active, still legally binding on FDA?

3) Does it pertain to livestock as well as crops? If not, please explain why?

4) Are there any guidelines for industry and public research agencies for abiding by this regulation? If so, can we be furnished a copy of those guidelines?

5) What is the history of FDA actions with regard to substances reviewed under this regulation since 1971?

In August 1974, Alan T. Spiher, Jr., then chief of FDA's GRAS review Board, explained:

> "A particular food widely consumed as a good source of Vitamin C, for example, might become less than a good source if replaced by a new variety containing much less of the vitamin. Tomatoes are considered a nutritionally significant source of Vitamin C. Data show that a recently developed new variety intended for mechanical harvesting, and the concominant marketing technique developed for this variety, delivers to the consumer a tomato having about 15% less Vitamin C content."

Spiher also noted another example:

> "Several years ago FDA was approached with data establishing that gamma radiation in doses about one tenth those approved for inhibiting sprouting would break the dormancy of seed potatoes and thus more or less double the yield from a given field by delivering two crops. We were asked to agree that there was no food additive problem. We inquired what would happen to the corp grown from the irradiated tubers: would the solanine increase? The proposal was abandoned when the laboratory results on a controlled experiments showed a 60% increase in solanine in the crop grown from the irradiated tubers compared to the crop grown from unirradiated stock."

We would like to know how many of these kinds of nutritional and/or toxic changes -- particularly in crops -- have been submitted to, or brought to the attention of, FDA since 1971. We would also like to know whose substances or products they were -- industry's, USDA's, or a particular university.

6). How many times has FDA exercised its authority to review crops or other substances for compliance with this regulation and what were the results?

7) What enforcement actions by FDA have been taken or formally recommended regarding this regulation since 1971? Have any industry, federal agency, or academic researchers been contacted by FDA since 1971 about new crop or livestock strains being developed that might fall into the purview of this regulation? If so, could a list of those actions and/or parties contacted -- together with the identified crop or livestock strain in question -- be provided to us?

8) Finally, what action, if any, is FDA contemplating with this regulation given the emerging application of biotechnology and genetic engineering to crops, livestock and agricultural microbes? Are not even greater changes in the composition and level of nutritional and toxic constituents in food crops and livestock now possible through the use of these technologies and genetically-engineered products released for use in agriculture and food procesing?

The Environmental Policy Institue appreciates the cooperation of FDA in providing this information. Our chief purpose in making this request is to obtain an accurate account of the history, current status and future applicability of the above cited GRAS regulation.

We look forward to your response.

Sincerely,

Jack Doyle

Jack Doyle, Director
Agricultural Resources Project

CC: Hon. Mark O. Hatfield
Hon. Thad Cochran
Hon. Thomas E. Eagleton
Hon. Bob Kasten
Hon. Henry A. Waxman
Hon. Doug Walgren
Hon. Timothy E. Wirth

c

Hon. Bob Traxler
Hon. Tom Harkin
Hon. George E. Brown, Jr.
Hon. Albert Gore, Jr.

Note: The Environmental Policy Institute, founded in 1974, is a non-profit research, educational and policy development organization operating under section 501(c)(3) of the Internal Revenue Code. EPI focuses on energy, water, and agricultural resource issues. EPI is involved in influencing legislation and government agency decision making, litigation, and conducts studies for use by citizens, industry and government agencies.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Washington DC 20204

JUL 17 1984

Mr. Jack Doyle
Director
Agricultural Resources Project
Environmental Policy Institute
218 D Street, S.E.
Washington, D.C. 20003

Dear Mr. Doyle:

Your letter to Dr. Novitch of May 2 has been referred to me for response. You raise a number of questions regarding 21 CFR 170.30(f)(2), formerly, 21 CFR 121.3(b)(2)(ii), which was published in the Federal Register on June 25, 1971. This subparagraph states that the following substances are eligible for inclusion in FDA's review of generally recognized as safe (GRAS) substances. The substances referred to are those that have had significant alteration of composition by breeding or selection and the change may reasonably be expected to alter to a significant degree the nutritive value or the concentration of toxic constituents therein. I shall paraphrase and address your questions in the order that you posed them.

1. Are there FDA documents pertaining to the basis for and history of this regulation, including minutes of meetings?

   I am sending you a copy of the proposal published December 8, 1970, and the proceedings of a symposium (Hort Science 10(3), June 1975), which address these points. This is the only information we have available.

2. Is this regulation currently active and still legally binding on FDA?

   The regulation remains current. I am enclosing a copy of the current regulation.

3. Does the regulation pertain to livestock as well as to crops?

   Livestock are not excluded from the regulation. However, I believe USDA would have primary responsibility with respect to livestock.

4. Are there any guidelines for abiding by this regulation?

   There are no guidelines.

5. What is the history of FDA actions with regard to substances reviewed under this regulation since 1971? How many of these kinds of nutritional and/or toxic changes have been brought to the attention of FDA?

   We have dealt with many inquiries regarding new varieties on a case by case basis. We have never maintained a list of inquiries on this topic and do not have the capability to generate such a list.

6. How many times has FDA exercised its authority to review crops or other substances for compliance with this regulation and what were the results?

   To my knowledge, FDA has never established a mandatory monitoring program for the purpose of checking the level of nutrients or toxicants in new varieties of food substances. I do know that potatoes were monitored on a voluntary basis, but this was done by USDA.

7. What enforcement actions have been taken or formally recommended by FDA regarding this regulation?

   I am unaware of any enforcement actions taken by FDA regarding the substances in question.

8. Finally, what action, if any, is FDA contemplating with this regulation given the emerging application of biotechnology and genetic engineering?

   The Center has an internal committee that is considering this issue. At this point, it is impossible to predict future developments.

Sincerely yours,

Sanford A. Miller

Sanford A. Miller, Ph.D.
Director
Center for Food Safety
and Applied Nutrition

Enclosures - As Stated

APPENDIX B

National Academy of Sciences
Proposal

May 1984

May 15-17, 1984 For Information

Environmental and Public Health Implications of Genetic Engineering

BACKGROUND: The following project proposal addresses a very significant and pressing problem. The proposal as drafted, also incorporates a carefully stqructured agreement with the Board on Basic Biology of the Commission on Life Sciences regarding joint management and oversight of this project. For background on the discussions with BBB/CLS that gave rise to the proposal, see Tab E.1. This proposal could set some important precedents for BA interaction with other units of the NRC.

The funding prospects for this proposal are excellent. Dr. Bentley has indicated on numerous occasions that USDA would be supportive of such a project if the project would address agricultural issues in an appropriate fashion. The project could begin by early fall, assuming that the proposal is approved by BBB/CLS, the BA, and the Executive Committee of the NRC, and funding is secured without great difficulty. Dr. Lasen and Dr. Benbrook will work together in approaching potential sources of funding.

NATIONAL ACADEMY OF SCIENCES - NATIONAL RESEARCH COUNCIL

Board on Basic Biology, Commission on Life Sciences
and
Board on Agriculture

Proposal for a Joint Study

Environmental and Public Health Implications of Genetic Engineering

SUMMARY: The Board on Basic Biology, Commission on Life Sciences, and the Board on Agriculture have identified the environmental and public health implications of the deliberate release into the environment of genetically engineered microorganisms, plants, and other products as a pressing issue of great importance. Potential commercial uses of genetically engineered organisms and products for a variety of purposes often entails their release in the environment. The Board on Basic Biology, together with the Board on Agriculture, proposes to organize a study of the biological, ecological, and agronomic principles governing the fate of genetically altered organisms and other products released in the environment.

The study will assess the scientific basis for predicting the likelihood and potential severity of adverse effects associated with the release of such organisms. An effort will also be made to establish the scientific principles that should underlie criteria to assess whether any special additional hazard might be associated with a product released in the environment when such a product has been developed and/or manufactured through a process utilizing genetic engineering techniques. There is a pressing need for better understanding of such scientific principles and criteria among federal agencies currently exercising oversight, research, and regulatory responsibilities in this area. The basis to undertake such an assessment is expected to be a matter of importance because many lines of research using genetic engineering techniques are expected to soon lead to commercial applications. To assure that scientific and regulatory resources are properly focused, it is important to differentiate genetically engineered commercial products posing new and unique risks from those products that are unique only, or largely because genetic engineering techniques were used in their development or manufacture.

The purposes of the project are to: 1) facilitate progress toward a consensus of judgment of the scientific community on implications of the release of genetically engineered organisms and products; 2) improve public understanding of the risks and benefits involved; 3) provide useful information and guidance for research and regulatory agencies, including EPA, NIH, NSF, USDA, DOE, and DOD; and 4) facilitate corporate planning and product development by helping to articulate the principles that should govern identification of appropriate and safe uses of such products.

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portant question that at least we have the opportunity to discuss with all of the agencies together, including—not just the regulatory agencies, but Department of Commerce, the U.S. Trade Representative that sit on that. We're asking questions. Are we adequately tapping into our own science base in developing this field, or are we going to be driving it abroad?

I think one of the big issues that—of concern about the introduction of microbes into the environment and the difficulties of trying to settle difficult decisions like that in the court is the ordinate delay that that develops and, or that that creates. And I think that's detrimental to our industry, and that has—there's a good chance for driving our industry abroad to do those preliminary tests.

So, I, I don't think our efforts will have a detrimental effect. I hope our efforts will have the opposite.

Mr. PACKARD. Thank you, Mr. Chairman. Thank you.

Mr. BROWN. Thank you, Mr. Packard.

I have a notorious reputation for being concerned about the adequacy of the science base and the knowledge base in general for regulatory and other needs as we move forward into new technologies, and I hope you won't think I'm nitpicking with my questions.

But, Mr. Kendrick, do you recall the circumstances in the Department of Agriculture when the Department had the jurisdiction over the regulation of pesticides and insecticides, and so forth, prior to 1972, I guess it was?

Mr. KENDRICK. Generally, yes.

Mr. BROWN. Do you feel that there was an adequate regulatory effort during that period?

Mr. KENDRICK. I believe hindsight will—would tell us that we probably could have done that a little bit better; yes.

Mr. BROWN. Hindsight is always better than foresight.

Mr. KENDRICK. Right. Yes, sir.

Mr. BROWN. It was the lack of adequate and aggressive enforcement of the existing regulatory structure that led to the creation of the EPA and the changes in the law that occurred at that time.

Now, Mr. Schatzow, has EPA made any recent mistakes? Have you had to recall any chemicals or insecticides or fungicides, or anything like that?

Mr. SCHATZOW. Have we, have we ever made a mistake in the licensing of a pesticide? Is that the question?

Mr. BROWN. Yes.

Mr. SCHATZOW. I believe we have. Yes, sir. [Laughter.]

Mr. BROWN. Do you recall a few examples off the top of your head from recent times where you had to cancel or recall?

Mr. SCHATZOW. Yes. Again, I question whether I would call those mistakes. But——

Mr. BROWN. Lack of adequate data base, wasn't it?

Mr. SCHATZOW. I would say that, yes, that we have had situations when we have not had adequate data when we've been dealing with existing chemicals and——

Mr. BROWN. Right.

Mr. SCHATZOW [continuing]. Have had to take them off the market when we've gotten new data in on those chemicals.

Mr. BROWN. Is EDB a good example of that?

In the 1970s, considerable controversy surrounded the burgeoning field of recombinant DNA research. Scientists voluntarily deferred certain kinds of research as a result of decisions developed at the Asilomar Conference; Congress came near to passing restrictive legislation on the research; public concern about the safety of the research was high.

Similar controversy exists now relative to the release and utilization in agriculture of genetically engineered organisms and other agricultural inputs. In a recent instance, genetically engineered forms of the bacteria Pseudomonas syringae carrying deletions of genes coding for proteins that enable bacteria to serve as ice nuclei have been proposed for use in controlling frost damage to plants. Such use was approved by the NIH's Recombinant DNA Advisory Committee, but legal action by concerned groups postponed field experiments.

In order to more fully realize the potential commercial and social benefits of genetically engineered microorganisms, plants, and other products, appropriate steps need to be taken to protect the public from unforeseen hazard. To do so, a close understanding is needed of the environmental and public health implications thought to be associated with different types of organisms and products. The purpose of this study is to analyze the basic scientific questions that must be resolved, at least in a preliminary fashion, in order to realistically structure responses to concerns regarding their safety and environmental fate. Such an appraisal is both needed and timely to support the development of sound public policies pertaining to research and development, licensing provisions, regulatory requirements, and a research agenda for risk assessments, as appropriate.

PROPOSED PLAN OF ACTION: A committee of about 15-20 scientists will be established by the Board on Basic Biology of the CLS (BBB/CLS) and the Board on Agriculture (BA). The membership of the committee will be approved by both the BBB/CLS and the BA, drawing approximately equal numbers from nominations provided by BBB/CLS and BA. The committee will have representatives of appropriate disciplines, such as microbiology, recombinant DNA technology, plant genetics, agronomy, ecology, evolutionary biology, soil science, limnology, public health/infectious disease, molecular biology, population biology, environmental sciences, plant pathology, entomology, climatology, etc. Because the questions regarding microorganisms and plants differ in many respects, it is likely two or more panels will be organized under the committee.

Early in the study, an information gathering workshop will be held to assess and better define the basic biological, ecological, and agronomic issues in need of detailed examination during the study. Presentations covering regulatory issues will also be made at the

May 17, 1984

For Action
Ad Hoc Subcommittee Membership

Identification of Board on Agriculture members for the ad hoc committee to be established to oversee the "Environmental and Public Health Implications of Genetic Engineering."

Pending approval of the project proposal, the board needs to identify three or four members to serve on an ad hoc subcommittee with members of the BBB/CLS. The subcommittee will assist the BBB/CLS and BA in administering the project, and undertake the detailed work entailed in selecting a committee to undertake the project. A motion to nominate three members, in addition to the chairman, will be in order, which will then be voted upon.

Nominees: 1. Dr. William Brown, Chairman

2. ____________________

3. ____________________

4. ____________________

Mr. **Brown**. Thank you, Mr. Doyle. We appreciate your contribution.

Mr. Volkmer.

Mr. **Volkmer**. Yes; I guess I could start off with Dr. Healy. There was a statement made by Mr. Doyle to the effect that the National Academy of Sciences wishes to make this study and that the OSTP has—or the Cabinet Council, I don't know which, supposedly has put a quash on that. What about that?

Dr. **Healy**. Well, first I must tell you quite simply that Mr. Doyle is seriously misinformed, and I'm concerned about where his sources are. Let me give you the information on the particular Academy study.

The Academy did come up with a proposal that came out of their Basic Biology Board and their Agricultural Board to get a group of scientists together to form a committee and to review the issues associated with biotechnology, particularly in agriculture and their effects in the environment. That particular study was summarized in a four or 5-page proposal in the broadest of terms. It had a $600.000 price tag associated with it, and the broad issue was to just look at what we know now about risk assessment.

I am sure Mr. Doyle did not mean to imply this, but that was not $600,000 to fund a new research and answer some of the uncertainties that Mr. Doyle has suggested we have in the area of microbial biology and ecology, but rather to get a group of scientists together to discuss risk assessment in this particular area.

We felt, first, that the price tag was a little bit high. We also felt that the proposal needed to have much more detail and to be scoped down on the specific approach, the specific issues that were going to be defined, the specific questions that would be addressed, and particularly since the Federal Government would be the funding source. At the same time the National Science Foundation, who, as you may or may not know, funds a great deal of the ecologic research that's going on in biotechnology, was also involved in developing a series of risk assessment evaluations for biotechnology, and we certainly didn't want a wasteful redundancy on these two efforts and felt it would be important that they be coordinated if they were both to be conducted.

We have in no way blocked the study, but asked the Academy to come back with a counterproposal. Additionally, we asked the National Academy to give us a COSPUP. The OSTP gets briefings from the National Academy on areas of importance, and on June 3 the National Academy of Sciences will be briefing OSTP on the very topic of biotechnology and agriculture. And again, the whole issue of where the Academy should interface in this very important broad issue of biotechnology, health and the environment will be addressed.

I think the most outrageous misstatement, however, that I wish for the record to correct is that OSTP blocked the study because it didn't want to broaden the debate. It is OSTP's great intention to have the debate broadened, and particularly with regard to the scientific dimension of this important area.

Mr. **Doyle**. If I may——

Dr. **Healy**. If I may complete this. I might also add that there is a strong effort within the Cabinet Council, another Cabinet Council, on risk assessment to take a broad look within the administration on risk assessment efforts in general. Mr. Ruckelshaus started that Cabinet Council effort on risk assessment; Mr. Thomas has intentions to continue that. And the National Science Foundation under Mr. Block and Dr. Kingsberry are particularly active in the area of risk assessment with regard to biotechnology. So I think contrary to what might have been suggested, we are very concerned about this debate being broadened and we are very concerned that the public, the scientific community at large all be involved in this.

Mr. VOLKMER. Mr. Doyle, we'll give you time in just a minute. Because I want to follow this up, and you can still respond. But I would like to find out, Dr. Healy, in your judgment—we're talking about the biotechnology in the microbial areas—is the existing scientific data base sufficient in determining the risk assessment in these areas?

Dr. HEALY. Well, let me—let me distinguish between the scientific information at hand immediately in a very general sense and the scientific processes that will enable you to get that information. The nature of science is, what drives science are questions that need to be answered, and we will never—there will never be a closed lid. Yes, we've gotten all the questions that are possible about the human gene, about animal genes or about plant genes. There will always be new information coming along or science has no meaning.

With regard to the particular area of microbial ecology, it is—I am not, although my background is in biology, I am not a microbial ecologist. But I can tell you from several scientists that are experienced in this area that there is much information that needs to be gathered. However, that does not mean that on a case-by-case basis, when you deal with a given microorganism in a given setting, that we don't have much information and that we also don't have the tools to get that information without having any great paradigm shifts or leaps of knowledge.

And let me also quote Marty Alexander, who Mr. Doyle quoted. And he has come up with a rather intriguing and simple scheme for assessing whether a microbe introduced into the environment—and I would stress the fact that these microbes that are introduced into the environment, the ones that are being used for the good of man, if you will, are handicapped organisms. These are organisms in which their whole metabolism has been shifted around—not for the good of the organism, but for the good of man—so it can produce all sorts of things like toxins it would never be producing in such huge quantity. So these are handicapped, severely handicapped organisms that usually don't survive.

But that's an important question: Is this organism handicapped enough so that it will survive? What Marty Alexander suggested is a very interesting and fairly straightforward model which said, ask the following questions:

What is the probability that the organism will be released into the environment? We have scientific, obviously, ability to answer that. We know, we can ask the question: Where are you going to put this in the environment?

No. 2, what is the survivability of that organism? That is a very straightforward question to determine whether or not that—how that particular strain compares to the wild type in terms of survivability.

Multiplication—will it proliferate? That's an easy question to answer if you're dealing in a case-by-case basis with a designated organism. You can look at it in the laboratory, and you can look at it and say, what, will it proliferate or does it, has it lost its reproductive ability? It's conceivable that some of these living organisms might not have their reproductive ability left. But that is a question that can be answered with existing scientific information.

Dissemination—that's a little trickier. If you introduce that organism into the environment, will it be dispersed and how far will it be dispersed? And probably certain specific kinds of experiments need to be done to determine how mobile that organism is or how it could be dispersed.

Transfer—will the genetic information be transferred to other species? There are ways that that can be tested. How stable is the plasmid? Can that plasmid exchange into other organisms in that same ecological niche?

And finally, and perhaps the most important question, will that engineered organism be harmful? It's not easy to answer that question if you look at the whole world of microbes. But if you talk about a little organism that has just been engineered to produce BT protein that you heard EPA talking about, you have a pretty good chance of saying that organism has no chance of being harmful to man, or has a small chance, or a big chance. And I think EPA already told you that they have experience with this and actually have relaxed all sorts of regulations on existing living organisms that are already out there in the market because they bear no relationship to human health.

So I think if you look at Marty Alexander's own scheme of the six scientific questions to be asked—do we have the knowledge or the means to get that knowledge today? I would say yes. I think that industry is working very hard, from what I can tell when they bring their proposals to the agencies, to try and ask those questions. And I think that it's the responsibility of the scientists within the regulatory agencies and on the review committees to say have they asked the right questions and have they given us adequate information of their uncertainties?

But to say in a general sense science hasn't gone far enough to deal with this area at all, I think is a misleading overstatement.

Mr. **Volkmer.** Do you believe that the full scientific community would agree with Dr. Alexander's assessment of how to, you used the word "assess," the microbial problem?

Dr. **Healy.** I think most microbiologists would ask those same questions. Is the organism survivable? Is it intrinsically harmful? Will it reproduce? I think those are very simple, straight—even as a cardiologist I've been asking the same questions, before I read the article.

Mr. **Volkmer.** Before I finish and let Mr. Doyle go, and I've got one other area, Mr. Chairman, in spite of my laryngitis, I want to get into. And that is, if this is the case, then what is the harm for NAS doing their study?

Dr. **Healy**. Oh, no. In fact, I would suspect that NAS will do its study. And we work—OSTP works very closely with the Academy and with Dr. Press.

Mr. **Volkmer**. You're just asking that it be more fine-tuned——

Dr. **Healy**. We don't want to waste money. We don't want to invest $600,000 in something which is redundant of something else that NSF is doing. We want the questions to be more targeted. And we think that it's an important thing that the Academy be involved in and do.

So, I would suspect that the Academy will be doing it. And actually the first phase of it, if you will, will be the June 3 briefing which we have asked the Academy to give OSTP on biotechnology and agriculture. That is part of the directions that we're taking toward the Academy broadening the debate, if you will, and being involved in the study. And actually, much of that proposal has very important merits. The notion of the Academy having a standing committee that deals with these issues.

I think the most important here is that we're not talking about an event that you can deal with at one point in time. The nature of this whole field of biotechnology is that it's dynamic and that it's changing and that there is always going to be new areas and new knowledge. What we have to have are mechanisms in place that can change along with it, that can monitor the change, that can cope with the change, and that can be flexible. And if anything, that's the thrust of the Federal Register notice with regard to the need for constant scientific monitoring and the need for interagency coordination, so that on an ongoing basis there's an opportunity for the agencies to get together, talk to each other and say what's new today in this field, rather than saying we have all the answers today, clamp, that's what we will do.

And finally, the most distressing part of Mr. Doyle's recommendations which he submitted for the record with regard to the National Academy report is the suggestion that we should basically stop. The OSTP proposal should not go forward until the National Academy proposal is funded and completed. Well, Lord knows how long that could take. I mean most of those studies done by the Academy take a minimum of a year's time. And quite frankly, Mr. Chairman, I don't think that the field of biotechnology would be well served or the American public would be well served if we put a stop on Federal involvement in biotechnology at the present time.

Mr. **Volkmer**. The last part, I'm glad you addressed that. But, the proposed regulations, of course, would be subject to change in the event that we learn something new in a year or 6 months or anything else?

Dr. **Healy**. You bet they are, and I think we say that in the Federal Register loud and clear. That we are not even saying that we don't need new legislation. We're just saying that right now we think we have the mechanisms in place and we want to define them. The Federal Register notice doesn't devise anything new, really, except it expands the Science Board and it proposes interagency coordination. It doesn't define new regulations. It says within the existing statutes that we have and the existing mandates. It defines how biotechnology products will be fit in. It does not devise a new regulatory matrix, it defines it; and, I think, that's a subtle but important distinction to make.

Mr. **Volkmer**. Mr. Doyle? I know you've been waiting patiently.

Mr. **Doyle**. Yes. I have several points here that I would like to bring up. First of all, in the attachment to my testimony, the proposed—my comments to OSTP, in appendix B there is the actual proposal from the National Academy of Sciences, so you can see, for yourself, what the Academy has to say and what the Academy offered for this proposal. I stand by the sources in the Academy who told me what OSTP's posture was toward this study. And I cannot divulge those sources because I think the person would be in trouble there if I did.

Now, I think, now, Dr. Healy made reference to an assessment study that Mr. Ruckelshaus had chaired, and I think that same assessment study was stopped by OMB when OMB interceded—and I refer this committee to page 25 of my comments, OSTP comments, the "Cabinet Council Involvement & Political History." I think it would be interesting for this subcommittee, for example, to make an inquiry into the history of this Cabinet Council Working Group. I mean, if you remember, EPA came before this committee in 1983, they started moving toward promulgation or development of some guidelines. There is a memo from OMB. There was a flurry of activity. In April 1984, we have a memo creating this Working Group and the study in 9 months time. So I think it's really important that this committee look at the political history of how this matrix has been devised.

I think, you know, there has been a good bit of work here, but there are serious omissions. And I will cite one very serious omission. I think that—I had a conversation with a person in AID who has, knows of microbial products being, nearing the—genetically altered microbials nearing field test stage that are funded by AID in foreign countries. And AID is not included in this matrix. They don't have a policy statement. I think that's a very serious omission, obviously, because of what might happen in a foreign country with a U.S.-funded project. We could be inviting a liability problem for our Government if something like, if an accident were to occur. Why isn't that issue addressed in this matrix?

Dr. Healy makes reference to the $600,000 price tag of the National Academy study. I would like to know what the OSTP has spent coordinating this activity over the last 9 months. And we could, perhaps, compare figures and find out. If you look at OMB's intervention in the assessment process, not only with this particular, with EPA's initiative, but with the other assessment capabilities that Dr. Healy referred to, I think if you factor in that delay there might be a cost associated with that that approaches the $600,000 or close to it. And second, I think that if NAS had been given the initiative in May 1984 when they first offered this proposal we may have a study right on our desk here now which would not be any more delayful than the OSTP document we have before us now, which is inadequate in our view.

And again, Dr. Healy makes reference to a briefing that's coming up in June by the NSF on this issue of agricultural biotechnology. And I think that's a good illustration of—why didn't that kind of thing occur before the framework was offered in the process. I think you, we have here a rush to regulation, or a rush to pseudoregulation. And I think we really need to take time and examine very carefully the scientific capabilities we have.

That's all I have to say, except for I think, I do suggest that the committee take a very hard look at the history of this Working Group. And I think now we have another question on the table. Just the other day we see that there is a consolidation of Cabinet Council Advisory Groups. How is this Working Group going to be affected? Is this process going forward? Is it—how is it going to happen? And what does it mean when we say that a final document will be published as soon as possible? Who's going to—when is that going to occur? Who's going to comment? Is the public? What's the Congress' role here? I mean we have I think just an inordinate list of questions here.

Mr. **VOLKMER**. Mr. Chairman.

Mr. **BROWN**. Do you have an additional question, Mr. Volkmer?

Mr. **VOLKMER**. I've passed, long post my 5 minutes?

Mr. **BROWN**. Oh, go ahead, take another minute. [Laughter.]

Mr. **VOLKMER**. I was going to ask that very same question, Mr. Doyle, of Dr. Healy. What is the status of the Cabinet Council? That wasn't going to be my next question. It was going to be my third one, but I'll put that second and put my second one third.

Dr. **HEALY**. Well, the Cabinet Council Working Group on Biotechnology will continue. It has not yet been decided under which of the consolidated Cabinet Councils it will fit at the present time, so I cannot, cannot answer that question. But it will be under one or the other, and it will continue its effort, and it will, has every intention of publishing its final notice as soon as possible.

I think the important thing is that the Cabinet Council Working Group on Biotechnology will not be changed by consolidation of the overall Cabinet Council structure.

Mr. **VOLKMER**. In other words, it won't be eliminated and their work put into another Cabinet Council made up of different people——

Dr. **HEALY**. No. The integrity of the exact Cabinet Council Working Group will be maintained. And I just also wanted to correct while we are talking about that the Cabinet—there is another Cabinet Council Working Group on Risk Assessment that I was referring to, Mr. Doyle, and not the OMB action on the Cabinet Council Working Group on Biotechnology. I do not know the status of that under the new administrative structure.

Mr. **VOLKMER**. Go ahead, Mr. Doyle.

Mr. **DOYLE**. Well, I mean historically I think there is a pattern you find that in this instance, I believe, and I can provide the committee with the articles that I've seen on this, that OMB interceded at the same time or it had already interceded on the assessment project that Dr. Healy refers to at the same time that it was interceding with the EPA proposal to regulate under TOSCA, and which led, subsequently, to the formation of the Cabinet Council the next spring.

But I think that, and I have some of that outlined in the comments on page 25, but I think that the subcommittee should investigate, look into that, because it gives you the decisionmaking process in the White House at the time, and I think that's important for the Congress to know.

Dr. **Healy**. I would urge you to look at facts rather than hearsay and patterns, however.

Mr. **Volkmer**. Well, I can look upon it, too, Mr. Doyle, as a possibility—and I don't know, perhaps we can look into it. But you know EPA is starting out, but we also have the FDA and Department of Agriculture and others in the same area, and whether you are going to try and harmonize, then bring it all together, instead of one agency going out front and none of the rest of them getting into the act. So, there's the possibility that that was the end result, too.

But I think I have a, maybe to me a little more serious question right now. And that is in the April 12 issue of "Inside the Administration," it states the Cabinet Council is likely to drop a proposal to create a new Governmentwide scientific board to review biotechnology projects. And the alternative proposal is to create a new arbitration board to, in other words, decide which agency handles this specific application. It says, "to resolve interagency and agency-industry disputes over biotechnology."

And I also find something very interesting in your proposed statement I guess I could call it, the one that was originally submitted to the committee, and the one given today, Dr. Healy. In the original statement that I have, on page 10, it says: "At this point the comments seem to"—that's the comments on the proposed regulation up through April 15—"seem to demand no major restructuring of the publication, but rather some fine-tuning in definitions and scope." And that sentence is left out of your statement today.

Now, does that mean that we're not going to just fine-tune?

Dr. **Healy**. Well, let me comment first. I also saw that report and "Inside the Administration," and all I can say is it's rubbish. I'd like to know where their—again where the sources are. But this isn't the first time that those little pieces of newsprint are outrageously wrong. I also called around my White House network to see if they were, if they had any rumblings this, and actually just yesterday spoke to Tim Weingarten at the NIH, and all of us are quite befuddled as to who even might have started such a rumor. But I can assure you that that report is nonsense.

With regard to the testimony, the reason why we took that line out is because we have gotten several more comments in since Friday, which I reviewed in preparation for the testimony today. And quite honestly I think that if the proposal would change, it may well change with regard to the structure of the science advisory mechanism, but in the opposite direction from what that little orange sheet said. I think, if anything, what we're hearing in the comments, and particularly some comments that came in in the past few days, is that the science mechanism should be stronger and that it should clearly have the clout of the existing NIH RAC.

That little piece on "Inside the Administration" took the totally opposite tack, and said all we need is some arbitration unit. I think that we're dealing with issues that are scientific and you don't need a group of arbiters, you need facts. Scientific facts and scientific information. So, if anything, I think the scientific world will be strengtened, not diminished.

The other reason for taking out, if you want me to be completely straightforward, for taking out that phrase is that, is the caution. Because I, on reflecting on the testimony, looking at it again before coming over this morning, we felt that it was probably slightly premature to make that statement until we had had a chance to look in detail at all 88—all 88 comments. So, I think that was a correction for the record.

Mr. VOLKMER. You didn't want to necessarily restrict yourself.

Dr. HEALY. You bet. Right.

Mr. VOLKMER. All right. Fine. And then we will see a Governmentwide scientific board, then?

Dr. HEALY. Yes, you will.

Mr. VOLKMER. Thank you, Mr. Chairman. And thank you, Dr. Healy.

Mr. BROWN. Mr. Packard.

Mr. PACKARD. Thank you, Mr. Chairman.

Mr. Doyle, if the administration does not proceed with the regulations, what would your recommendation be in terms of products and companies that are ready to move forward and would be delayed in that process waiting for the Federal regulations for biotech industry?

Mr. DOYLE. Well, with Ralph Hardy sitting here from BioTechnica, I know that there are companies that would be frustrated by that, but I think that in the long run the Nation has—I think it's in the best public interest. I mean we're faced with five products at EPA right now and are being reviewed. I think that we need to have a careful scientific evaluation before thousands of products come to our agencies. I think that it's in our best interest to be prudent here. I think it's the reasonable course. The National Academy is our highest science body, it's objective. We need—I mean the whole impetus for this OSTP is coming from the White House. So the Congress has, outside of a few hearings, the Congress has not done, has not taken the initiative in this area as well.

So I think, and I think the figures that I've just heard for the first time today from Dr. Healy on the response to the OSTP, I mean 88 responses. You know, that's—we just need to have a broader debate. I mean if you go forward and finalize something with 88 responses, and I forget what the number was for the average citizen, but I think we need a much broader debate on this. This is a revolutionary technology that we have here. I think we just have to, have to be prudent.

I can appreciate the frustration of companies that have products. And I visited BioTechnica, in fact, and others, in the conduct of my research, and there is exciting science going on. It's very exciting. And we're excited by it, and we think there'll be some real important potential for agriculture. But I think in the interest of prudence we should be a little cautious here.

Mr. PACKARD. Thank you.

Mr. Kendrick, do you feel that the existing regulatory framework is adequate to evaluate and regulate the biotech research and products which fall under the USDA's jurisdiction?

Mr. KENDRICK. Yes, we do.

Mr. PACKARD. You would leave it in place the way it is?

Mr. **Kendrick**. Right now, with the regulatory authorities that we have, yes, we feel we can deal with what we see coming onstream in these products of the new biotechnology. Yes.

Mr. **Packard**. The—let me go to Mr. Shat-tous? Shat-tou?

Mr. **Schatzow**. It's close enough. Schat-zo.

Mr. **Packard**. Schat-zo. Thank you. I apologize.

Mr. **Brown**. A good Irish name. [Laughter.]

Mr. **Packard**. Given that agriculture biotechnology results in genetically altered living organisms, how reliable are the laboratory impact assessments in determining how the organisms will respond to the environment?

Mr. **Schatzow**. I think many of the, the questions that we want answered in terms of the ecological effects that there are procedures that can be done in the laboratory that can give us a fairly good handle I think on how the organism will react in the environment. I think the kinds of questions that Dr. Healy was referring to in terms of Marty Alexander's article are—that we can develop, and people are developing new specific laboratory tests to be able to reduce the levels of uncertainty in terms of the areas of survivability, reproducibility, as it relates to organisms that might be released.

Mr. **Packard**. What procedures do you have now in place that you would use to assess the impact of genetically engineered organisms, and what effect they would have upon the environment and upon our own well-being?

Mr. **Schatzow**. We have a series of guidelines and a series of protocols for testing microbials. They're published both as regulations in terms of the types of tests, and they're also published in terms of guidelines in terms of protocols for conducting those types of tests. Again, we're merely dealing with an extension rather than a whole new field when we're talking because we have been dealing with microbials for many years.

Mr. **Packard**. Um hum.

Dr. Hardy, what are the differences, in your judgment, in the normal crossbreeding processes that we've had in existence for generations with plants, and the difference between that process and the genetically engineered plant process? How do those differ, and is there more or less uncertainty about the effects that the genetically engineered plant organisms would have as opposed to the traditional crossbreeding process?

Mr. **Hardy**. I think you've identified clearly the key question: Is the process different or not, and then what is the end result? The processes are clearly different. In organismal genetic engineering one can come up with, as was earlier referred to this afternoon, southern corn blight. And what one was trying to do was find an easy way to make hybrid corn. And it just so happened that in getting the materials that you needed to make hybrid corn, during those genetic manipulations you just happened to have dragged along a sensitivity to southern corn blight that you didn't know about. That's what I call a random approach. That's what we've been doing for decades. And the random approach can have its problems, and southern corn blight is an example of those problems; albeit, we were able to quickly correct the situation and one was able to go back to more traditional hybridization methods. So, it was not a major disaster, but it, I think, clearly illustrates the problem of organismal or traditional plant breeding.

In genetic engineering by the molecular route, you identify a specific gene that will make a specific product and insert it into the plant. You know exactly what you've added to the plant. You have predictive capability that you don't have in the other situation. You would not have, for example, in producing the hybridization situation, you would never have brought along the genes to give you sensitivity to southern corn blight.

So, the progression is from a system that's a, if you will, a crapshoot, which we've been using for years—we don't know what's going on—to a situation where, in fact, we do know what's going on. The record I contend is pretty good even though the crapshoot. That suggests, then, that the hazard that's associated where we know what's going on is not going to be a great one.

And there are a lot of histories of genes that, in nature, have fluidity. Genes do move around in nature, and I think that's, in the last decade to two decades, one of the things that's been surprising. So, naturally genes are in a flux. Those have not created major disasters for us. Here we have a technology that we know exactly what's going on, and I contend that the risk is even going to be less than it's been with the traditional organismal engineering.

Mr. PACKARD. From the private sector's point of view, and I noted that you wanted to respond to some of the discussion between Mr. Doyle and Dr. Healy, how—again, as a company point of view, how do you perceive the proposed regulations in view of further studies?

Mr. HARDY. Let me——

Mr. VOLKMER. Dr. Hardy, would you please pull the microphone closer?

Mr. HARDY. I'm sorry.

Let me go back a step earlier than that. Let me put on another hat. I sit on both the Board on Basic Biology and the Board on Agriculture in the National Academy. We did have and do have a project called EPHIGE, which is the project that has been under discussion. I've been at almost all the meetings of the Board on Agriculture and all the meetings of the Board on Basic Biology in recent times. I'm aware of nothing of the reports that came to us that indicated that there—the OSTP or other agencies were trying to stop this project from going forward. So that, it's a project I think was a very interesting one 2 years ago. I have some questions of whether that activity at this time would provide a lot of benefit. That I think information has been gathered in other ways during that period of time to question the utility of a report that probably would not come out till 2 years from now.

Most Academy activities that I've been associated with take a year plus. The report that I referred to earlier today, the "New Directions in Bioscience," that report we tried to do on a rush basis, and that took about 1½ years.

Two of the committee members that sat on this report chaired the COSPUP Committee that is just in the process of meeting and will report to, to OSTP in June on ag biotechnology. So there has been an activity that's been going on within the Academy that does, in fact, relate to the biotechnology area.

Mr. **Packard**. Thank you.

Dr. Healy—one last question, Mr. Chairman, if I may—do you feel that the proposed regulatory framework would favor the larger companies in the biotech area or disfavor the smaller companies? And the second part of that question, do you believe that it would have any effect, or could have? Is there any part of those regulations that would have a detrimental effect upon our companies being able to compete with foreign research companies?

Dr. **Healy**. Your first question is a difficult one because I think that the issue of a large company versus a small company, quite frankly, never came up, except in the very broad recognition that smaller companies clearly need more than any to have a well-defined regulatory pathway. Because they can't afford to send teams of lawyers to Washington to knock on every regulatory agency door to find out where they go to get a product approved or licensed.

But it was our belief that even large companies, not just small companies, should not be wasting unnecessary dollars because the Government can't get its act together. So, although only in the very broadest sense did the issue of large versus small come up, the bigger concern of the Cabinet Council, which is, are we doing our job right? Are we providing clear messages and clear signals that will enable industry to efficiently deal with the regulatory agencies and that will not deprive the American people of the benefits of something which they've been investing billions of dollars in over the past 10 or 20 years?

So, to answer your question, the large and small issue came up, but only in an indirect way.

With regard to the detrimental effect, is your question do the regulate—do what we propose, would that have a detrimental effect?

Mr. **Packard**. I'm concerned about any set of regulations as to how it will affect the private sector in terms of competition in the world market place, and I don't think our research can be excluded from this concern.

Dr. **Healy**. I think there's no doubt that if we don't have as a first step a clear regulatory message out there to industry that we are going to have a detrimental effect. And that's why I quoted the President's Commission on Industrial Competitiveness. Those people said it better than I. That if we don't have—if we have regulatory chaos, that is going to be our worst enemy in terms of our economic advantage and our international competitiveness.

The extent to which this document in its attempts—I don't think it's perfect, but in its attempts to try and put at least an orderly first step in place, I would hope that it would have a favorable effect. I think it's important to stress, however, the Cabinet Council does not believe that dealing with regulation is the only way to deal with our international competitive position and that we must also take into account the issue of harmonization of regulations internationally, we must address some of the trade issues, some of the R&D issues, some of the concerns about whether or not we're adequately taking advantage of our own internal tech transfer from the basic science laboratory out into industry.

Many other countries are very skillfully using our basic science advances and base in their own industrial development. And an im-

Mr. SCHATZOW. The EDB is a good example of a chemical for which we were for a lengthy period of time lacking a variety of data, particularly exposure data on that chemical.

Mr. BROWN. Exposure data. Diffusion in the environment, too, wasn't it?

Mr. SCHATZOW. Yes. We were lacking exposure data both in terms of where in the environment, was it in food, was it in ground water? And we found out it was.

Mr. BROWN. Are you caught up on all your data call-ins, and so forth, that you're doing now to repair some of those deficiencies?

Mr. SCHATZOW. Well, we're very actively involved in a variety of data call-ins. I don't know about what "caught up" might mean. We're committed to completing data call-in on all food use chemicals for all core studies, all chronic studies. For all food use chemicals, completing that data call-in by the end of fiscal year 1985. That started predominantly in 1984, and we are most of the way through that. We're doing a major exposure call-in this year.

Mr. BROWN. I'm making the point here that you're not really caught up and free from mistakes in the area of chemical regulation, and yet you express great confidence in your ability to regulate—as do you, Mr. Kendrick—in an area in which we have very little data.

Mr. SCHATZOW. I'm not—I guess I'm not convinced how little data we have in the area of microbials. And I think the point is that at any point in time we may have hindsight. The facts are that——

Mr. BROWN. We're trying to produce foresight.

Mr. SCHATZOW. I understand that. And all we can do I think at any point in time is to assure that the chemicals or the biologicals that we may allow on the market are fully scrutinized according to the best science we have at that point in time. And I think that is exactly what we're doing right now with the genetically engineered organisms.

Mr. BROWN. I think that you're undoubtedly correct.

Dr. Hardy, do you recall how many years it took for the oil and automobile companies to figure out that there was any hazard from lead in gasoline?

Mr. HARDY. I can't answer that question specifically.

Mr. BROWN. I can. It took at least 30 years before they recognized it. And during that time they testified there was inadequate data as to the health effects.

Mr. HARDY. I would respond I think, Congressman Brown, that we've had decades and centuries of experience in genetic engineering. I don't see molecular genetic engineering as being greatly different in endpoint than organismal genetic engineering.

Mr. BROWN. I gathered that from your testimony. But is it possible you could be wrong?

Mr. HARDY. It's possible that anyone can be wrong. One I think has to base decisions on the best track record that's out there. And what's worried me in this area is that most people have tended to ignore a record that I think is fairly substantial at this stage. We've—there's the indication that this is a totally new area. That the end product is a totally new end product.

Mr. **Brown**. Well, I think what you're trying to do, and I commend you for it, is to prevent an atmosphere of irrationality producing a regulatory environment which is unnecessary.

Mr. **Hardy**. Exactly.

Mr. **Brown**. I just don't want you to overdo it.

Mr. **Hardy**. I appreciate that.

Mr. **Packard**. Would the chairman yield briefly?

Mr. **Brown**. Certainly.

Mr. **Packard**. I'm intrigued by your questions, and more by the implications that might be taken from them. And that is, would you suggest, or are you suggesting that we should not have received and enjoyed the benefits of gasoline for 30 years not knowing that lead might be harmful, and therefore implying that perhaps maybe the benefits from this kind of technology might—may need to be delayed until we know all the answers?

Mr. **Brown**. I don't quite see that as an implication of what I was saying. I was suggesting that there develops certain vested interests in any operation in which a big investment has been made and a reluctance to see the adverse impacts because of that, and that we need to avoid that happening when we can.

Mr. **Packard**. I certainly would not disagree with that.

Mr. **Brown**. Mr. Schatzow, or Mr. Kendrick, who regulates the inoculation of Rhizobiums? That was mentioned, I think you mentioned it, Dr. Hardy, in either leguminous plants or——

Mr. **Kendrick**. We do not regulate. They're not regulated.

Mr. **Brown**. And you don't regulate it, do you?

Mr. **Schatzow**. Not to my knowledge, no.

Mr. **Brown**. Nobody regulates it, do they?

How about—what basis in law do you use for regulating the, the ice-nucleating bacteria?

Mr. **Schatzow**. Since it is a bacteria, which it affects the growth the growth of the organism and it affects the longevity of the organism, and therefore we say it's a pesticide.

Mr. **Brown**. You consider it a pesticide?

Mr. **Schatzow**. That's right.

Mr. **Brown**. You feel pretty sure that it's a pesticide, huh?

Mr. **Schatzow**. We feel pretty sure that it's a pesticide.

Mr. **Brown**. You don't——

Mr. **Schatzow**. Growth regulators generally and specifically under the Act——

Mr. **Brown**. This isn't a growth regulator. This is an ice-nucleating bacteria.

Mr. **Schatzow**. It is an ice-nucleating bacteria, but it has properties I believe that are similar and have to do with regulating growth and regulating longevity.

Mr. **Brown**. You have drawn some parallel reasoning here I guess.

How about——

Mr. **Schatzow**. I haven't seen any questions, I guess, being raised as to whether we have authority under the act.

Mr. **Brown**. I might raise that question some day.

How about nitrogen fixation bacteria? If we were to be able to convert one that now works for leguminous plants and the one that works for wheat or corn, would you regulate it? And if so, under what provision of law?

Mr. SCHATZOW. I haven't looked. I can't respond.

Mr. BROWN. Do you have any ideas on that, Mr. Kendrick? Would the Department of Agriculture——

Mr. KENDRICK. We would not regulate it. We've been working with those organisms for years. Now, if by definition of the new biotechnology it was modified, and because of the concern of the new biotechnologies, we would make sure that it received the review process under this system that we've been working with for years. In our Ag Recombinant DNA Research Committee, if DNA was the technique that was used to modify the organism, we would review it to make sure that we weren't introducing a new virulence, pest-type, and go on with it.

But we know enough about the organism. We've been working with it for years, and as Dr. Hardy has said, it would be very—very quickly. You would have, you could predict what was going to happen.

Mr. BROWN. Under what provisions of law would it be regulated?

Mr. KENDRICK. Under the Plant Pest Act, is the one that we would apply.

Mr. BROWN. You have decided that a nitrogen fixing bacteria is a plant pest?

Mr. KENDRICK. No. I would say you would look at it under that one. For the most part, very quickly you would look at it and probably decide that it didn't need any further regulation. But if the, if biotechnology was used to modify it, because of the concern that the public has that this is some dangerous technology, we would do a review process, make that review public, and go on with the research.

Mr. BROWN. Dr. Healy, are you convinced that the existing law adequately covers all of these situations where it isn't clear to me that there is applicability of present law?

Dr. HEALY. Well, I think that after looking at the existing regulations, an exercise that we did—and laws—an exercise that we did very early on in the Cabinet Council Working Group was to come up with a list of possible biotechnology products that would be hitting the marketplace, any ones that are even imagined. And we went through the exercise of trying to see if we felt that they were laws under which these products would get appropriate attention. And we were looking actively for gaps in legislation, and at this point we have not come up with them.

That doesn't mean, however, that in science—with science and all its wonders that there might be a very different answer a year from now. And I think for that reason we believe strongly that the Cabinet Council Working Group or some other body like that needs to continue to ask that question in an active and regular basis and in a forum of informed people who know the regulatory law that's out there because I think that could change.

Mr. BROWN. I agree with you on that. I am, as a matter of fact, pleased with the progress that I see, but I detected a certain atmosphere of what is sometimes called hubris I think. That's when you laugh at the gods.

Dr. HEALY. I hope not.

Mr. **Brown**. And I don't like to see that happen. For example, in connection with FIFRA, I've been trying for 3 years to do something to obtain changes that are generally agreed to be necessary by the industry, chemical industry, agriculture, even the administration; and yet, the administration hasn't proposed any changes basically because they don't want to open the law up and subject it to amendments they might not like. Now, I think something like that is going on here, frankly. I don't want to confirm everything Mr. Doyle said, but I think there's a possibility that that exists in this situation.

Dr. **Healy**. Well, I, I would—let me just make a comment in that regard. I think that I have not detected hubris within the deliberations of the Cabinet Council Working Group, and I certainly hope it's not there. And I think hubris is a devastating quality for any scientist in particular.

Mr. **Brown**. Absolutely. Politicians, too.

Dr. **Healy**. It is devastating for a politician, and it's devastating for a Government official, in general. It actually is a bad trait in Washington that's all too common. So, to that extent, I would agree with you.

But I think that the important thing is that we keep acknowledging the fact that there are uncertainties both in the scientific realm and also in the realm of whether—what wonderful product will come along tomorrow that is not adequately dealt with.

And if I may make a comment about the Congress. In all truth, Congress has done a very good job in keeping the hubris titer low. Because I think that the administration knows well that if we don't get our act together and we don't see to it that we are active in aggressively pursuing these products as they hit the market and seeing that they are dealt with with adequate review of their safety for the society that Congress will be in there and developing legislation.

And there's nothing wrong with legislation. We're not in the least bit opposed to legislation. We have 17 or 19 pages of it in there that we're using to answer your questions. But the issue is that in this field that's moving so quickly you don't want to get locked into a law that might reduce the flexibility that you need at this point when things are moving so quickly. We want to do our job well, and we're happy to work with the Congress in trying to do it well. And I think that just the nature of that interchange suggest that maybe there isn't a great deal of hubris involved.

Mr. **Brown**. Yes. Well, I recall that several years ago, 2 or 3 years ago at least, when the Supreme Court handed down the *Chakra Bardi* decision they indicated there was certain needs for the Congress to act in the field of impaired organisms, and so far I haven't seen any indication of any recommendations from the administration on that. Maybe they're waiting for the Congress to act, I don't know.

That doesn't deal directly with the regulation of risk. It deals with the patentability of living organisms. But the principle is the same. The Supreme Court said that this is an area in which, obviously, the Congress had not enacted legislation because the situation was new. And I agree with you that we shouldn't precipitously legislate, but it is also necessary that we not delay legislating when it becomes clear that it would be useful to legislate. And that's the point that we're trying to determine.

Dr. **Healy**. And the point that I think we all agree on.

Mr. **Volkmer**. Would the chairman yield just for a minute? I know we got another panel. And I think the chairman's questions and statements have really been on the point. He's done very well; better than I could do.

I was curious, Mr. Kendrick, when you brought out when the chairman asked about nitrogen fixation on application of certain plants you are presently unable to do it, et cetera. You would be able to review it. What if you had an industry out there that came up with something, whether it's for soybeans or something else now, that enhanced it, and didn't bother to come to you at all, just go ahead and started marketing the new enhanced seed that has this new fixation already implanted in it? What are you going to do?

Mr. **Kendrick**. Well, Chairman Volkmer, in this national biological assessment system, or program that I mentioned, that I said is essentially a formalization of a system that's been at work out there for many, many years, the industry that might develop this, and they're working at it and they have been working at it for a long time to introduce improved products, that industry would have tested that in the public system along the way. We may not have known the, some of the proprietary information, but they would have put it into the public system, tested it to make sure it was an acceptable product. They wouldn't just—otherwise, they'll never market it.

Mr. **Volkmer**. They could put it in their own test plots.

Mr. **Kendrick**. They have their own test plots. But I think Dr. Hardy will bear me out in saying that they will never—they will never market that without having tested it in the public system at the experiment stations alongside of other products that we know are in existence, because they want that public acceptance of it. But my guess is they would not do that.

Mr. **Volkmer**. The other little question that Mr. Brown brought out that I'm interested in. Bacteria is not a pest, is it?

Mr. **Kendrick**. Many bacteria are pests and many are not. Pathogens.

Mr. **Volkmer**. All right. Thank you, Mr. Brown.

Mr. **Brown**. You have been very patient, and we won't beleaguer you any longer. Thank you very much for your testimony, and I think you've contributed to our better understanding of this very important subject.

Our last panel is Dr. Robert Kalter, chairman of the Department of Agricultural Economics at Cornell, and Dr. George Kidd.

Would you two gentlemen please come forward?

STATEMENTS OF ROBERT KALTER, PH.D., CHAIRMAN, DEPARTMENT OF AGRICULTURAL ECONOMICS, CORNELL UNIVERSITY, ITHACA, NY; GEORGE KIDD, ADVANCED SCIENCE CONSULTANT, WILLIAM TEWELES & CO., MILWAUKEE, WI

Mr. **Volkmer**. Mr. Chairman, I was just wondering if Dr. Kidd—Dr. Kalter or Dr. Kidd, whoever is going to show the slides, whether it's the latest family or vacation, or what the slides are for.

Mr. **Kidd**. Maybe ice minus bacteria.

Mr. **Kalter**. I think I'm going first, Mr. Chairman.

Mr. **Brown**. You may proceed, Dr. Kalter, and if you wish to summarize your statement in view of the lateness of the hour so you can get home earlier or anything, why, you may do so.

Mr. **Kalter**. All right.

Mr. **Brown**. The full text will appear in the record.

Mr. **Kalter**. Thank you, Mr. Chairman. I do have a summary. I am accompanying the summary with a set of slides which I hope will illustrate some of the main points that I've got to make this afternoon.

Mr. **Brown**. Can we have somebody control the lights?

Mr. **Kalter**. Let me first introduce myself. I'm a professor and chairman of the Department of Agricultural Economics at Cornell, and I'm also the chairman of the Cornell Biotechnology Program Committee on Economic Development which we think is a unique committee in this area that is composed of representatives from industry, the State government and Cornell dealing with technology transfer and doing economic research on potential impacts.

[Slide.]

What I wanted to stress this afternoon was the implications of some of the biotechnology products being looked at for agriculture with respect to policy, and particularly, towards the end of this discussion, with respect to the 1985 farm bill.

[Slide.]

Let me first give you some background of where we're coming from and what we think are important factors here. Clearly there is a set of major potential benefits that are going to accrue because of biotechnology in agriculture. We think that they are in the area of improvement of productivity or efficiency, improved product quality and releases of resources for alternative uses, which some people I think will not view as a benefit, but perhaps as cost, and we can talk about that a little later.

I think the difference that we see here from past technological advances in agriculture, which are all very familiar, is that we are now beginning to look at a compression of the time scale in particular areas, so that we can have major and massive increases in productivity in very, very short periods of time. I'm going to discuss at some length this afternoon bovine growth hormone, which you'll see is about to give us 40 percent increases in productivity during the time that it's administered, and that increase in productivity takes effect in 3 to 5 days. And this is something that before would have taken us generations of breeding to achieve. So, we're looking at a difference from past technological advances in the sense that we're compressing that time scale.

Potential costs of this are similar to what we've experienced in the past, but again they're going to be experienced more rapidly. That is, economic dislocations, people having to leave the farm; equity impacts; and alterations in our overall structure, et cetera, within the industry.

[Slide.]

Now, specifically on agriculture, as I indicated, we've got possibilities of some very significant impacts, but most of these are, right now, largely in the future. The major economic impacts are not yet commercial products. Largely, R&D is our current phase of development.

Timing of the new products, that line is incorrect. It should be "uneven," not "even." We think very strongly that the timing of new products will be very uneven. We are likely to see some new products that are going to have major impacts within the next couple of years. Other products may be in the 1990's, after 2000. So, we don't think this is all going to come at once. We're going to have to look at individual sectors and be very specific about our research and what the potential impacts are going to be.

We're already having, as you've heard all afternoon, major impacts on industry planning and on university activity and government regulatory decisions. I won't belabor that.

[Slide.]

Long-term impacts of this we think are going to be quite pervasive. It's not just the normal changes in productivity within a particular activity in agriculture that's concerning us at Cornell, but it's everything from price support programs in agriculture to land use to crop rotations to conservation to local government finance, believe it not. Because if land values change, it looks to us like we're going to have some implications for local government finance. So, there is a whole spectrum of possible implications that we need to start taking a look at from a policy perspective.

I've generally grouped these concerns in this research into three areas: plant production, food processing, and animal production. And I think we're a little bit unusual at Cornell, at least in our department, in that we think that the first widespread applications with major economic value are going to be in animal science rather than in plant science. We're pretty convinced now after our research that this is the key area of the immediate future.

The impacts I think are going to vary with the product, and so we feel very strongly and one of the key points I want to make as background before we talk about a specific is that we are having very—a lot of difficulty generalizing from a specific example to a general set of trends. We think that a lot of the impacts are going to have to be looked at individually and uniquely with respect to a product like an animal product or a crop product, and they're going to have different implications depending upon their characteristics, their capabilities, and their working attributes.

[Slide.]

Now, our research at Cornell—can I get that focused a little bit—is, in the last 2 years has been concentrating on bovine growth hormone because we think the hormone is perhaps the animal science product that is closest to the market and will have the greatest impact of anything we've seen so far. We're looking at a series of factors involving growth hormone. If hormone is technologically feasible, which it appears to be, is it commercially feasible? How much does it cost to produce it? So, we looked at production costs. We looked at the commercial potential then given those costs. We looked at the impact on farm profits. We looked at the farm management implications, because, again, I don't want to bore you with details this afternoon, but we think it's very important to understand how this product will act on the farm so we can better forecast from the micro effects what the macro effects will be.

We're looking at the adoption rates; that is, how rapidly once it's released into the market will farmers adopt it, and therefore how fast will the impacts take place. Then the market implications. And finally, the national dairy policy implications.

[Slide.]

Now, if you can read that slide, it's a little fine print, but this is a specific example of the production costs for bovine growth hormone given various plant capacities. If—this is a standard industrial fermentation process, so it's quite easy for us to cost out what it's going to—what the economics are going to be. And we're looking at plants here capable of producing anywhere from one-half million to 7 million doses of this hormone per day.

The cost per gram is the important factor on the slide. Notice that it goes from $4.23 a gram down to about a—just under $2 a gram for the larger size plant. The importance of that is that we have tremendous economies of scale in producing this product, and so we're concerned that there's the opportunity for monopoly profits by the industry that would supply this to agriculture. And with monopoly profits, of course, we're going to get a reduction in the benefits to the agricultural sector that we get out of this.

The reason there's opportunity for monopoly profits is that as your production costs come down with scale the first company that is going to get FDA approval is going to be able to go to large-scale plant and essentially collar the market for a period of time, and then when a new company gets FDA approval they are going to have a very tough time entering and maintaining a competitive posture because the existing firm can lower its prices to exclude, and it's going to have a lot of room to lower prices.

[Slide.]

So, we're concerned about the opportunity for monopoly profits. We think that's an important policy question. We're concerned that the regulatory approval process is going to be very important to reduce the possibilities for these monopoly profits by assuring entry of more than one firm at a time and by promoting competition in supply.

[Slide.]

Now, the dairy—let me turn to the dairy farm implications very quickly. And what we did is we looked at the possibility of the hormone being introduced in three representative farms in the northern part of the country: New York, New England, the Great Lakes States, et cetera. What about our large dairy belt in the United States? Not California, however.

We wanted to look at the maximization of return over variable costs, which is the way most farmers operate. We wanted to look at the implications of the hormone on forage compositions; on adjustments to the feed rations, which appear to be very important; on the sensitivity of the ration reformulation, which will affect concentrate versus forage and therefore crop rotations, which is the next item; on purchase feeds; on labor requirements; and on changing milk prices. What the implications would be for changing milk prices.

[Slide.]

I will by pass all the detailed specifics that we have in a very large report we just issued from Cornell, which I can make available if you're interested, and just try to summarize.

The purchase feed requirements increased dramatically. The concentrate particularly increases; that is, the use of soybean and corn in the ration. We have to feed those animals more to get the increase in milk production from this hormone. As I indicated, the hormone in trials at Cornell is producing 40 percent increases in milk production within the space of 3 days. Now, that increase is not over the entire lactation because we've been administering the hormone from peak production to dry, and that translates into about a 25 percent overall increase in production for the whole lactation. But still very, very substantial increases almost overnight.

But we do have to feed the animal more, and so we're getting tremendous increase in concentrate costs and feed requirements due to this injection. Therefore, a major change in crop rotations might be required on most farms. We see changes from corn silage to hay, for example, on our larger farms in our sample that are dramatic; to the tune of sometimes 50 to 100 acres within a farm, switching from where they would have been without the hormone to where they will be with the hormone.

Very little change in labor or capital. This is a low capital intensity requirement. It's a daily operating cost basically with a very quick response, and so we don't need any more capital and very little additional labor.

We increase our profitability substantially, as you will see in just a minute, at current milk prices. And I want to emphasize at current milk prices. Profit increases less than production. We, for example, if we get 25 percent increases in production, we increase our profit about 20 percent roughly. If your increase production less, obviously the profit goes down.

The two important things that stand out in this part of the study are the last two items on the slide. There is an absolute premium on farm management ability. Very clearly the best managers are going to be advantageous, or this is going to be an advantageous product for them. If they are not good farm managers, if they can't balance their rations, if they can't do their crop rotations correctly, they're in trouble.

And secondly, there is a premium on land resource quality because we have to feed more concentrate, so therefore the farmers with the better land resource are going to have an advantage, a comparative advantage over those who cannot grow corn for grain, for example.

[Slide.]

This is a slide which just indicates the change in farm profitability. Very quickly, on the far left zero, no BGH, no growth hormone; and on the far right, 40 percent increase in production during administration. This is for our midfarm, our corn grain farm, midsize farm out of the three. And notice we have a nice even progression of profitability at $12.69 milk prices. This is what that slide is predicated on.

[Slide.]

Now, the gainers, to summarize, are going to be the early innovators, the excellent managers, and those with good soil resources.

[Slide.]

The losers are going to be the noninnovators, the ones that are poor managers, those with poor soil resources, and those that are highly leveraged. Because as milk prices start to come down with this increased supply, people that have large mortgages are going to be in trouble trying to pay those off.

[Slide.]

Now, that slide is a little difficult to see, but let me just explain what I'm trying to do there. There are three downward sloping lines representing our three farms, and that's the return over variable cost. At the far left is the 12.69 price, and as you go to the right, the price drops down to 8.50 a hundredweight. This is per hundredweight of milk. And as you'd expect, the return over variable cost falls as the price for milk in the market falls.

The horizontal lines which are bisected are those farms' fixed costs. So, this is a 13,000 pound average herd, and notice for a forage only farm at $11.50 this farmer's return over variable cost falls below his fixed costs. So, he is essentially living off his capital at this point. For a larger farm, a corn grain farm, he's not in trouble until about $9.75 a hundredweight. And for a very large farm that sells corn grain off the farm with crop sales, he's not in trouble until you get down to about $8.75. So, this gives you a nice neat portrayal of what happens as milk prices start to drop.

Mr. **Volkmer**. Could I interrupt, Mr. Chairman, on that just a minute?

Mr. **Brown**. Sure.

Mr. **Volkmer**. And leave that slide up there.

Mr. **Kalter**. I've switched to the next one. I don't think this has got a back—wait a minute, it might do it. No.

Mr. **Volkmer**. OK. Let it go.

Mr. **Kalter**. Can you switch back to—I can do it. OK.

Mr. **Brown**. Mr. Volkmer.

Mr. **Volkmer**. I just ask if you have one up there where you have the dairy farmer that raises no feed and is going to have to buy all, and has in the past purchased all his feed, and now he's going to have to go more to beans and corn?

Mr. **Kalter**. That's the lower line, Congressman Volkmer. It's the forage only farm. That farm can only raise hay or corn silage. He cannot raise corn grain or soybeans. And so that farm represents a case I think that you're discussing. He has to buy all of his concentrate basically off the farm.

Mr. **Volkmer**. All right. Now, how much would that be?

Mr. **Kalter**. Well, I'll have to go and look at my specific numbers, but his costs jump dramatically; in the area, as I recall from memory, about $15,000 or $20,000 a year for concentrate costs. I can give you a specific number on that.

Mr. **Volkmer**. Of course depending on price of beans and corn?

Mr. **Kalter**. That's right. And there're some assumed prices here.

[Slide]

This is the same slide for a 16,000 pound average farm before BGH, and notice that the line switch to the right—the intersections of the line switch to the right, so that the forage only farm now is not getting himself into trouble until about $10.50 a hundredweight, and the corn grain farm is OK up until about $8.75, and the larger farm never gets into trouble even at $8.50 a hundredweight.

So, the instruction that you get out of these results is that these poor soil resource farms really have a problem, and also the farms that can sell corn grain off farm are going to be at a comparative advantage position compared to those that can't because they can increase their concentrates from internally grown material.

[Slide.]

The adoption rate is critical now because, if we're getting this kind of increase in productivity, the question is how rapidly will farmers adopt this technology, and therefore how much of an impact will it have on the market. What we did last summer was to survey about a 1,000 New York State dairy farmers on what they would do if this was introduced in the market. We didn't get that kind of a response, but we got about 200 responding, about 1 percent of our dairy farmers. And subsequent to our survey, Auburn University took the same survey and conducted it in four States in the South—Florida, Mississippi, Alabama, and Missouri—and got virtually identical results to ours, as I recall.

[Slide.]

And what we found was that the adoption rate was going to be exceedingly rapid. That the cost of the product, of course, was going to be important as well as the delivery system. If it has to be injected daily, the adoption rate was not quite as rapid as if it had an implant device, but the difference was not significant. That the production orientation of the producers was very important, and that's a key factor.

Not only did we find that the adoption would be rapid, but it would be most rapid by those with the largest herds. And so this implies again that we're going to have a very substantial market impact very quickly after this comes on the market. We think we could have 95 percent adoption within 3 years considering that the number of farmers are going to have to leave agriculture, or at least leave dairy farming, and the nonadopters we think will have to leave much earlier than the adopters. And therefore, if you look at it from that perspective, we think we might even have close to 100 percent within 3 years.

If you understand the technology adoption questions, and I'm sure you all do very well, this is an exceedingly fast adoption rate for agriculture. We've only experienced something faster in my recollection once, and that's in poultry with New Castle disease vaccine, which actually took place in about a year.

[Slide.]

This is a graph showing how rapid the adoption takes place with implants, on the bottom, in months: 6 months, 12 months, 24 months, 36 months. Notice this is from our survey. Within 36 months we've got about 87 percent adopted, and this is all the farmers in the sample including the ones that we think will leave after a period of time.

This is the same graph with injections. Slightly lower but still about 84 percent by the third year, by 36 months. So, this just confirms what we're saying.

[Slide.]

The magnitude of the adjustment, therefore, we think is unprecedented. It's going to depend upon productivity; that is, do you actually get 40 percent response rates on the farm given farm management. We're very skeptical of that on the average. But even if you get 20 percent or 30 percent, we think it's going to be adopted rapidly. Profitability, now how rapid will milk prices come down. FDA approval is the timing question. We're expecting about 2 years now before FDA approval. Probably this will hit the market around '87 or '88 the way we look at it right now.

[Slide]

Now, market and policy implications. Milk prices must fall for the market to regain equilibrium. I think every economist will preach that and believes it. The result of a fallen milk price is going to be a reduction, and a major reduction in this case, in national herd numbers. We're currently at 11.2 million milking cows. We're anticipating that that may have to fall as low as 8 million at equilibrium after this market comes back into some kind of focus.

The dairy farm numbers and the milk output also must fall, obviously. And I think overall we're projecting a possibility of from where we are now to equilibrium after growth hormone is introduced. Well, there's as much as a 25-to-50 percent reduction in cow numbers and farm numbers in the dairy sector. An absolutely dramatic change——

Mr. VOLKMER. Where?

Mr. KALTER [continuing]. In the space of a very short period of time.

Mr. BROWN. May I interrupt you?

Mr. VOLKMER. Where?

Mr. BROWN. Where?

Mr. KALTER. OK.

Mr. BROWN. May I interrupt you at that point?

Mr. KALTER. You bet.

Mr. BROWN. Just taking the cow numbers and assuming the statement that you made about the large farmers introducing this more rapidly, large, better managed farms, doesn't that imply that a much larger percentage of total farm units will actually have to go out of business?

Mr. KALTER. You're absolutely right, Congressman Brown, there's no question about it. I've couched my percentage very carefully. We're not exactly sure who's going to go out because one of the problems is some large farmers may be leveraged even more than some small farmers might be. So consequently, you've got to look very carefully at the distribution of farms by size across soil type, and we just don't have the answers specifically on that. But there's no question that you're going to have to have more of an attrition in numbers than just the percent increase in production.

Mr. BROWN. And we have a 10-percent overproduction now?

Mr. **Kalter**. That's about correct. It's about correct. And these values are based upon taking that into account.

OK, let me continue. We, therefore, think that farm legislation, particularly the 1985 farm bill, must consider the possibilities of such a rapid change in productivity in order to at least get the trend going in the right direction; that is, to bring the market back into some equilibrium before a growth hormone enters the market. I think the price support programs must encourage inefficient and highly leveraged farmers to either exit the dairy sector or possibly to change to an alternative enterprise on their land. Hopefully we could get alternative enterprises, but that's not going to be easy.

Major consideration we think must be given to this, but I think we also feel that major consideration must be given to retraining for nonfarm employment for those who want to leave the farm. Some type of safety net now has got to be put up, it seems to us, to soften the fall that's going to take place.

Now, I don't want to end saying, in fact, that we've got a disaster on our hands. I'm very optimistic about this new technology. This is a set of productivity changes, which I think in the long run are going to benefit the country, and going to benefit agriculture, and they're going to benefit those that remain in agriculture. What we're concerned about is that policymakers understand the timing of this new product, how rapidly it's going to come on and what the effects of it might be, and that they prepare for this in the current legislation that's being considered so that we ease, if we can, the dislocation impacts on farmers that we know are going to have to leave the sector.

And with that I'll turn it over to Dr. Kidd, and we can—I think both of us can stand for questions or however you want to go.

[The prepared statement of Mr. Kalter follows:]

STATEMENT OF ROBERT J. KALTER, PROFESSOR AND CHAIRMAN OF THE DEPARTMENT OF AGRICULTURAL ECONOMICS, CORNELL UNIVERSITY, BEFORE THE HOUSE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT OF THE SCIENCE AND TECHNOLOGY COMMITTEE, APRIL 17, 1985

Mr. Chairman:

I appreciate the opportunity to speak to the Subcommittee today about the potential impacts of biotechnology on agriculture. By way of introduction, I am a professor of Agricultural Economics and chairman of the Department at Cornell University. I am also the chairman of the Cornell Biotechnology Program's Committee for Economic Development. Cornell's Biotechnology Program, funded by a combination of New York State and private industry funds, is unique in that it has established this committee to explore the issues of technology transfer and to undertake research on the economic impacts of the new biotechnology for agriculture. The committee is composed of members from Cornell, industry and New York State government agencies. The economic research conducted under this program is carried out by faculty members within the Department of Agricultural Economics.

During the past two years my colleagues and I have been conducting in-depth research on the impacts of a biotechnology product for agriculture - the bovine growth hormone. My testimony this afternoon will focus on this product as an example of the potential impacts of biotechnology for agriculture and agricultural policy.

BACKGROUND

First, however, permit me to provide some general background which can serve as a framework for this discussion. The "new biotechnology" continues the long history of technological change and innovation so familiar to agriculture, which has resulted in more efficient production processes, improved product quality, and released economic resources for alternative uses. To an economist, biotechnology implies the opportunity for productivity change, expanding the output of goods and services and ultimately improving the world's living standard.

However, advances from biotechnology research, like those in electronics, have the potential to differ from previous technological innovations. Biologically, the difference stems from the possibility of accelerating the rate of productivity change beyond any previously experienced. The new biotechnology is based on understanding the fundamental chemistry of life, and it implies the potential compression of time required to develop new products or genetically advanced species.

Economically and socially, rapid acceleration in productivity change can have both beneficial and adverse ramifications. The benefits to society, if the promise of biotechnology is realized, are improved efficiency, better product quality, and a higher standard of living. On the other hand, the speed with which new products or processes are commercialized may affect established methods of conducting the world's agricultural business, bringing dislocations, equity impacts, and alterations in social structure. In the short run, productivity improvements can rarely be made without disadvantaging some economic sectors or individuals while improving the economic condition of others.

Recent advances in biotechnology suggest the possibility of significant impacts on agriculture. The probable extent and nature of the resulting economic changes are of major interest to both public and private decision makers. It is important, however, to realize that the future effect of biotechnology on agriculture is largely uncertain. With few exceptions, research and development are the current stages of activity. Only a few new commercial products or processes have appeared, and none are in widespread use. Most researchers point out that progress toward commercialization will be uneven over time. Adoption rates will depend on a host of exogenous factors particular to the affected industry segment, as well as on the nature of the development itself.

Although rapid and widespread commercial use of new advances would appear to set the stage for dramatic structural change in agriculture and the food industry, the impacts of specific biotech research are likely to differ greatly as to degree, timing, and the industry segment affected. As a result of the size, complexity, and diversity of agriculture and the food industry, general forecasts are difficult.

Observers often discuss potential impacts in relation to existing institutional structure. Issues include how biotechnology will change specific components of the industry, educational institutions, and government. The questions raised by proposed biotech applications range from land use to marketing, from price support policy to the structure of agriculture. The impacts will transcend conventional institutional lines, perhaps resulting in new institutional mechanisms or major changes in institutions themselves. Public and private decision makers who recognize trends and possibilities early will be in a position to minimize costly short-term adjustments and dislocations, facilitating transition to a more productive agriculture.

RESEARCH DIRECTIONS

Substantial research is now underway to apply new knowledge and information. The possibilities are limited only by the human imagination. Three broad categories are plant production, animal production and food processing. Changes in any of these areas are likely to have side effects on industries that supply inputs to agriculture.

We believe that application of the new biotechnology to animal production could result in the first widespread use of new techniques to enhance productivity. Revolutionary biotech developments relying on recombinant DNA processes can lead to rapid changes in animal productivity. These new biological tools offer lower production costs for naturally occurring substances useful in regulating animal physiology and health, promising far-reaching economic implications for agriculture. Forecasting the precise impacts must depend on the detailed knowledge of each new product's characteristics, capabilities, and working attributes.

For example, widely published reports have recently implied that use of a biotech product -- bovine growth hormone -- would cause a regional shift in dairy production toward the southwest and west. I suspect that these forecasts result from an incorrect assumption by those carrying out the analysis that bovine growth hormone administration results in additional milk production with no increase in feed intake. Although early short term trials would appear to have indicated such a "something for nothing" phenomenon, long term research indicates that animal feed intake must increase in proportion to the additional milk produced. Therefore, the comparative advantage of newer dairy producing regions is considerably reduced.

BOVINE GROWTH HORMONE: AN EXAMPLE OF BIOTECHNOLOGY'S POTENTIAL IMPACT ON AGRICULTURE

Bovine growth hormone (bGH) is a naturally occurring protein produced by dairy cattle. It is one factor regulating the volume of milk production. The gene responsible for its production in animals causes minute quantities to be manufactured by the pituitary gland. Consequently, the isolation and extraction of the protein from animals is expensive, time consuming and limited to the quantities which can be obtained from the pituitary glands of slaughtered animals.

However, the gene responsible for bGH production has been isolated and transferred from animal to ordinary bacteria cells. The altered bacteria can then be reproduced on a large scale by standard fermentation techniques and the resulting growth hormone (which is produced by the bacteria) can be isolated, purified and made available for commercial use. When injected into dairy cows at the rate of 44 milligrams per cow per day, the hormone has resulted in significant increases in milk production. Recently, Cornell researchers have completed long term trials utilizing recombinantly produced bGH with demonstrated responses in milk production ranging as high as 40 percent during the period of injection.

With this type of potential, various private sector firms are investigating the commercial production of bGH. Several have announced their intention to bring bGH to the market as soon as 1987 or 1988. Commercial introduction requires Food and Drug Administration (FDA) approval. However, it seems likely that the approval process will be expedited in light of the product's potential and the fact that it is a naturally occuring protein. Careful study of this potential product can result in the identification of a number of possible impacts, policy implications and developing trends. I would hesitate to argue that the resulting lessons can be generalized, but the approach can provide a valuable technique for examining other biotech developments.

PRODUCTION COSTS FOR COMMERCIAL bGH

If the technical promise of bGH is realized in on-farm use, the economic viability will initially depend on its market price. Market price cannot yet be predicted accurately. However, the cost of production can be approximated using standard cost engineering studies. Using such techniques, a price floor can be established and compared with possible returns to determine whether the product has a chance of commercial success.

A cost engineering analysis of fermentation facilities for bGH production using genetically engineered bacteria was conducted by Cornell's Department of Agricultural Economics (in conjunction with the Department of Chemical Engineering). Particular attention was given to the size of production facilities required and whether scale economies would exist. The estimated plant capital and operating costs were then subjected to a comprehensive evaluation of economic and financial feasibility.

The resulting price to produce is clearly related to plant size indicating that substantial economies of scale exist. Production costs ranged from $0.18 to $0.08 per cow dose (production facilities of 0.5 million and 7.0 million average daily doses, respectively). Reasonable changes in key variables did not have a major impact on production cost economics when converted to a per dosage basis. Plant profitability is highly sensitive to minor absolute changes in dosage price although the percentage change may be substantial. However, selling prices for the hormone will be higher than the dosage costs given due to marketing costs, mark-ups through the distribution chain and, perhaps most importantly, the cost of hormone purification and enhancement. For example, use of implant devices for delivery, rather than daily injection, could substantially change the effective selling price.

If commercial viability is tied to production costs, a tentative evaluation of bGH's potential can be given. To sustain a cow receiving bGH, more feed will be required and hence higher feed costs will result. Assume for sake of argument that, for an average cow, the extra feed costs for an additional pound of milk induced by bGH will average between 4 and 6 cents. If one conservatively assumes that bGH will stimulate an additional eight pounds of milk per cow daily, the marginal revenue received at prices as low as $9.50 per hundredweight would be adequate to support the commercial introduction of bGH.

However, substantial scale economies appear to exist with respect to bGH production. This suggests that a single large manufacturing facility is economically preferred if market monopolization is not a factor. Conversely, it implies that monopoly power could develop with the resultant effect being bGH market prices substantially higher than production, marketing and delivery costs. The impact on farm profitability, adoption rates and, ultimately, on milk markets is unknown (depending on the amount of economic rent that the conferred market power would permit the firm to extract). None-the-less, substantial opportunity appears to exist for monopoly profits on the part of bGH producers and, therefore, reduced returns to agriculture. The regulatory approval process and its timing with respect to the offerings of competitive firms can be a critical factor in assuring entry and promotion of competition.

ECONOMIC IMPLICATIONS FOR REPRESENTATIVE FARMS

The rate of bGH adoption by individual dairy managers will depend on a number of factors in addition to product cost. The potential response in productivity, ease of inclusion in overall herd management, and actual response under a variety of management situations will contribute to profitability and extent of usage. To provide a basis for analyzing the "macro" implications of bGH, we have evaluated the potential impact on dairy production at the "micro" or farm level.

Potential profitability of using bGH is investigated by analysis of three representative dairy farms. These three farms are constructed to represent the broad diversity of resources available to dairy farm managers in the Northeast and the Lake States. The resources on these representative farms, cost and return information from enterprise budgets, and milk production and feed requirements with and without bGH are used to obtain profit maximizing enterprise levels. Results are then used to analyze farm firm level issues including:

- What is the potential effect of bGH on farm profitability?
- Does profitability vary with assumptions on feed intake response of the dairy cow?
- Are there significant differences in profitability from using bGH among the representative farms?
- What are the impacts on crop rotation patterns?
- What are the impacts on farm profitability as milk price is reduced?

The three representative farms consist of a 200 acre, 65 cow, forage only farm, capable of raising mixed mostly grass hay and corn silage; a 250 acre, 100 cow, corn grain farm, capable of raising mixed mostly legume hay, corn silage and corn grain for farm use; and a 400 acre, 100 cow, crop sales farm, raising mixed mostly legume hay, corn silage and corn grain for farm use and sale. Since milk production per cow is highly variable and crucial to the analysis, each representative farm is evaluated at an assumed no bGH production level of 13,000 and 16,000 pounds of milk sold per cow.

The optimal ration for each farm, production level, stage of lactation and for each of five bGH response levels (no bGH, and 10, 20, 30 and 40 percent response during administration) is formulated for three alternative forage compositions. [Note that since bGH has usually been administered post peak production, the response values studied average 6.4, 12.8, 19.2 and 25.6 percent, respectively, over the entire period.]

IMPACTS ON THE FEED RATION

Based on recent Cornell trials, it is felt that the feed requirements of a lactating cow being administered bGH could change in one of two ways:

- Voluntary feed intake changes are insufficient to support increased milk production. Thus, diets need to be reformulated at higher nutrient densities to support the nutrient requirements. This adjustment implies that intake response is insufficient to avoid increasing the energy density of the rations. We will call this the normal intake assumption.

- Voluntary intake increases such that the diets formulated for the early lactation period are of sufficient nutrient density to support the increased daily milk production during the treatment period. This alternative implies that intake response is sufficient to allow feeding of the same diets but for different periods of time. We will call this the enhanced intake assumption.

Table 1 presents the results of the feed ration model for a representative case. The results portray a significant increase in both costs and profits per cow with bGH administration at an assumed milk price of $12.69 per hundredweight. The total intake of feed increases less rapidly than the increase in milk production, especially with normal intake assumptions. As a result, the nutrient densities of the rations must increase, resulting in larger proportions of concentrates. **Concentrate cost increases dramatically, and as concentrate prices exceed forage costs, total costs are proportionally greater than production increases. Because the enhanced intake requirements presume bGH results in extra stimulation to both production and intake, the increases in concentrate and total cost are moderated. Return over feed and milk marketing costs shows a dramatic increase, although usually proportionately less than the increase in production.** In percentage terms, results do not differ substantially with changes in either hay crop quality, forage composition of the ration or the production level of the herd.

The true test of bGH will be the return over feed and marketing costs compared to the cost of obtaining and administering it. Table 2 provides a perspective on profitability. **As shown, with milk prices of $12.69, the return exceeds the costs for all combinations at both response levels shown. This return is available for bGH purchase, administration costs and enhanced profit.**

IMPACTS ON REPRESENTATIVE FARMS

In analyzing the impact of bGH, it is important to realize that a change of this magnitude in feed rations has ripple effects throughout the farm operation. In addition to the expected changes in feed requirements and profitabiilty, crop acres, feed purchases and/or sales and labor requirements may change.

Using the enhanced intake assumption and the 16,000 pound initial herd production average, the general impacts of the overall farm operation can be represented. These results adequately mirror the general impacts of the analysis for all farms and situations. Table 3 summarizes these results. **The return over variable costs increases with increasing response to bGH. The increase ranges from just under 5 percent for all farms at the 6.4 percent response rate to 25 percent at the 25.6 percent response rate.** At any given response rate, the economic benefits of administering the hormone are similar across the three farm types. **On a per cow basis, increased return is the greatest on the large farm with corn grain sales and decreases progressively with farm size. Likewise, the increase in return per hundredweight of increased milk production increases with farm size.**

On the other hand, marginal feed costs per hundredweight of milk production generally decline as production response to bGH improves. This is not unexpected since the ration is not reformulated, and the greater the production response the greater the benefit of the intake assumption. The resulting values range from 3 to 6 cents per pound of production. At high response levels this marginal cost is more than a dollar a hundredweight less than the normal intake assumption. The savings result from the greater use of forage.

Purchased feed requirements increase on all farms as response rates increase, and for the 400 acre farm corn grain sales decline. Purchases are substantially below those with the normal intake assumption. At the 25.6 percent response, net feed purchase increases are 15 (crop sales) to 42 (corn grain) percent less. **The crop acres adjustment is dramatic on the large farms as land shifts from from silage to hay production.** Finally, the marginal returns to cows and associated facilities are uniformly higher with increased response rates. The marginal return to land is generally stable across all scenarios.

All of this points to the fact that the farm management ability of individual operators will be absolutely critical to the successful economic use of a product like bGH. To achieve the maximum response rates from bGH, crop rotations must be modified, feed purchases and sales realigned, and, most importantly, feed rations and intake must be adjusted to provide adequate nutrient intake. **Since management ability is generally not considered a size neutral characteristic, farm structure will undoubtly continue to move toward larger, more capital intensive, dairy operations.** However, new biological technologies will probably not require the capital investment at the farm level needed for mechanization, free stall barns, no-till cultivation, etc. Farm costs, such as operating expenses, will be relatively low, encouraging adoption. Expenses will be quickly recaptured and will often reduce unit costs. **The resulting incentives for quick adoption and the potential disruption of markets by oversupply will, however, place the highly leveraged farm operator at a financial disadvantage.**

It is also clear that skill requirements will increase. Specific products may involve methods and equipment dissimilar to those currently in use. More generally, higher productivity will lead farmers toward increased management of farm operations as opposed to the execution of farming tasks. Changing skill requirements for farming will depend in part on the interaction of new biotechnologies with advances in agricultural applications of other technologies such as microcomputers.

RESPONSE TO CHANGING MILK PRICES

Biotechnology advances will occur in an agricultural market currently growing more slowly than the overall economy. It is in the context of relatively static and generally inelastic demand that biotechnology is likely to affect the market for agricultural commodities. At least in the short run this can be expected to put downward pressure on consumer prices and farm incomes. The most interesting question, then, relates to the implications for changing marginal values when market prices for milk respond to increased production. Figures 1 and 2 portray the return over variable cost and the return over all costs for different milk prices. The direction of the change in returns is obvious. In all cases, the percentage decline in returns substantially exceeds the percentage change in market milk prices. For example, a 33 percent reduction in milk prices results in a return over variable cost reduction which varies between 44 and 54 percent.

For all farms, returns over variable costs fell below the no bGH level with a $1.00/cwt price decline at 12.8 percent bGH response rates and with a $1.70/cwt decline at 25.6 percent response rates. **Thus, a 14 percent reduction in the market price for milk is sufficient to make all farmers worse off even with a 25.6 percent bGH production response.**

In order to provide further insight into the impact of the change in price, fixed costs are estimated for each of the representative farms. Total fixed costs, including operator labor and management, a capital charge, depreciation, property taxes and insurance, are $70,000, $90,000 and $95,000 for the forage only, corn grain and crop sale representative farms, respectively. **Figures 1 and 2 depict the point where returns over variable costs, for each farm, are no longer sufficient to cover fixed costs.**

As milk prices fall, cow numbers will drop nationally. Since any reduction in cow numbers saves the maintenance portion of the feed ration, the implication is that less land area will be devoted to dairy enterprises. In the aggregate, one would also expect the demand for corn and other concentrates for use in dairying to fall. Alternative enterprises will need to be developed for this land which will probably consist of areas with relatively poor soil resources. Other biotech derived products may assist in developing uses for this land. For example, modification of important plant varieties to permit their production in shorter growing season regions would aid the development of alternative enterprises on our poor soil resource areas in northern New York.

SUMMARY

The administration of bGH and the subsequent production response will result in major changes in dairy cow enterprises and some adjustments in crop rotations. Total feed requirements increase although less than proportionately with production response. If a farm's crop acres remain constant, the extra feed requirements result in increased feed purchases and/or decreased crop sales. Changes in the required forage are generally met through changes in the cropping program.

When intake is assumed to respond in a normal pattern, the total forage requirement decreases and forage acreage generally declines. Purchases concentrate increases two to four times as rapidly on the forage only and corn grain representative farms. On the crop sales farm, corn grain sales decrease dramatically. With the enhanced intake assumption, more forage and concentrate are required. Increases in purchased feed are ameliorated since more nutrients are provided by an acre of forage than by an acre of corn grain. For farms similar to the forage only farm with no surplus forage, forage purchases would be required with bGH.

With stable milk prices, return over variable costs to the representative farms increase 5 to 26 percent depending on farm characteristics and response rate. The return over variable cost per cow increases with response rate, is greater for higher base production, is greater with the enhanced intake assumption, and is greater for the crop sales representative farm. Marginal values are generally constant on land and associated machinery and increasing on cows and buildings.

As aggregate production responds to bGH administration, milk price will fall reducing or erasing the short-term increase in returns (subject to governmental support programs). When cow numbers decline sufficiently to eliminate the resulting over supply of milk, prices should adjust upward but will not regain former levels. **The financial position of individual farms after these adjustments will depend on the ability to actually achieve response to bGH, the success of feeding management strategies to increase intake, the current financial position and use of short-term returns from bGH, and the economic and political environment of the industry. Clearly those farms with the least financial leverage and the better soil resources (because of the need for increased feed concentrate) will be in a better position to survive the initial fall in market prices.**

THE ADOPTION ISSUE

A factor key to determining whether the adjustment to a new equilibrium will be rapid and difficult or gradual and smooth is the rate of acceptance of bGH by dairy farmers. Despite the impressiveness of the test results for bGH there are reasons to believe adoption would be more gradual than some expect. Historical experiences with other farm innovations suggest farmers may perceive obstacles to adoption that are not apparent to outside observers. In order to facilitate planning for the dairy sector under the prospects of such major technological change, it is necessary to formulate expectations for the rate and extent of bGH adoption.

Predicting the rates of adoption and diffusion for an entirely new product such as bGH is necessarily a speculative exercise. The only relevant source of information is the judgment of potential users, in this case dairymen. The problem of obtaining useful indications of an innovation's attractiveness consists both of communicating the innovation's potential advantages and disadvantages as well as eliciting meaningful reactions from potential users. For generating a prediction of dairy farms response to bGH, a survey procedure was developed that involved both these elements.

A two-tiered sampling procedure was used, consisting of 40 personal interviews in seven representative New York dairy counties followed by a mail survey to 1,025 farmers. The overall response was 173, or about 1 percent of all New York dairy farms. The characteristics of respondents match closely State averages, suggesting that the sample is representative. **Results show a rapid adoption rate with at least half of the State herd on treatment within the first year of bGH availability. An 85 percent level of adoption is achieved by about the third year. However, our approach did not account for downward price effects of widespread use of bGH. Should bGH become widely used and prices allowed to adjust, it is unlikely that nonadopters could survive. Thus, in a dynamic environment, we expect use of bGH to approach 100 percent within 3 years after** introduction. These survey results have been confirmed by similar surveys in other parts of the nation.

Early adopters are characterized by having, on average, larger herds. Therefore, not only is individual adoption response rapid but that response takes place in a manner that assures a more than proportional increase in marketable milk. Requiring further analysis are the price effects of various rates of adoption and possible policies to manage the effects of rapid increases in milk supplies.

MARKET AND POLICY IMPLICATIONS

Rapid increases in milk production will have equally dramatic impacts on milk prices, farm and cow numbers and the government price support program. With the milk market currently in a surplus position even without bGH, milk prices will need to fall in order to reduced national herd numbers and milk output. With bGH, the adjustment process will be far more difficult, require substantially greater reductions in prices, cows and farms, and make adjustments in the federal dairy support programs critical in reaching a new equilibrium.

For example, we are estimating that, in the short-run, milk prices, cow numbers and farms may need to fall by as much as 25 to 50 percent in order to restore equilibrium market conditions after the introduction of bGH. The precise changes will depend on a host of factors, including the actions taken to restore market equilibrium in the next several years, the elasticity of demand for milk, the bGH adoption rate and the production response obtained by adopting dairymen.

Postponement of actions necessary to eliminate the current over production situation will only compound the problem two or three years from now. Development of farm policy in 1985 must look ahead to the possibility of rapidly changing productivity after 1987-88 That seems to imply a two prong approach to the dairy surplus problem.

First, a revised price support program must recognize the future possibilities and set support levels so as to encourage inefficient and/or financially leveraged dairy farmers to exit the dairy sector. The widely discussed $11.60 per hundredweight support level might provide such an incentive if the period available for adjustment was sufficiently long-run. Unfortunately, this does not appear to be the case. With productivity enhancements like iso-acids and bGH becoming available later this year or within the next several years, respectively, time for orderly adjustments may be slipping away.

Second, therefore, major consideration must be given to mechanisms that would assist displaced dairy farmers in either developing alternative enterprises on their land or in obtaining retraining for non-farm employment.

CONCLUSIONS

If approved by the Food and Drug Administration, bGH is a viable commercial product for increasing milk production from dairy cows and improving short term dairy farm profitability. Production costs for the recombinantly derived hormone are low relative to other factor inputs and the marginal cost per hundredweight of additional milk produced ranges between 25 and 45 percent of the current price paid to farmers. This coupled with potential productivity increases which could reach 25 percent or higher with well managed herds provides the basis for rapid adoption of the product.

Surveys of dairymen indicated the strong probability of rapid adoption and further suggest that large herds will most rapidly implement this new approach to increasing milk production. If, as indicated by survey results, 80 to 90 percent of the dairymen adopt within the first three years of market availability, unprecedented implications for farm management practices, milk markets and prices, and farm structure will follow.

At the dairy cow enterprise level, total feed requirements will increase although less than proportionately with production response. On a farm firm level, this will result in increased feed purchases and/or decreased crop sales. Depending on the feeding management program and production response by the animals being administered the hormone, requirements for concentrate will increase from 30 to 110 percent. As a result, crop rotations will change to accommodate the need for more nutrients. Overall, with stable milk prices, farm returns over variable costs increase 5 to 26 percent depending on farm characteristics and the response of animals to hormone administration.

In the aggregate, as production increases due to the hormone, milk prices will fall reducing the short-term gain in farm returns. The number of dairymen and the size of the national dairy herd will, by necessity, decline as the market seeks a new equilibrium. The size of this adjustment and its timing will depend not only on the production response to bGH and the rate of adoption but on the level and scope of government price support programs for milk. **However, with the possibility of such a rapid and large production increase, many dairymen, in the three to five years after hormone introduction, will be placed in the position of obtaining returns over variable costs which are below their fixed costs of operation. Farms with low debt loads, good soil resources, and superior management will be better able to survive the transition. The financial position of individual farms after these adjustments will depend on the ability to actually achieve response to bGH, the success of feeding management strategies to increase intake, the current financial position and use of short-term returns from bGH, and the economic and political environment of the dairy industry.**

In summary, it is becoming increasingly clear that biotechnology will greatly alter the speed and direction of technological change in agriculture. Farm production, agribusiness, research, education, and public policy are likely to undergo dramatic changes, the ultimate results of which cannot be predicted with any degree of accuracy. But potential areas of change and general trends are coming into clearer focus. How public and private decisions will combine to respond to the new challenges will determine how society benefits from their research investment. What needs to be understood is that biotechnology is beginning to shape the private and public policy agenda, now and increasingly in the future.

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Table 1

COMPARISON OF PERCENT INCREASES IN FEED REQUIREMENT BY RESPONSE TO bGH AND FEED INTAKE ASSUMPTION FOR BASE CASE[a]
(percent)

Annual Requirements, Costs, or Returns	12.8% Response		25.6% Response	
	Normal Intake	Enhanced Intake	Normal Intake	Enhanced Intake
Production	12.8	12.8	25.6	25.6
Concentrate Cost	44.7	21.5	96.4	43.4
Total Ration Cost	15.9	14.1	34.9	25.4
Return Over Feed and Marketing Costs	11.2	12.1	20.7	25.7
Total Intake	4.7	10.7	10.0	17.6

[a] 16,000 pound production without bGH and forage half from corn silage and half from MML.

Table 2

PER COW INCREASE IN RETURN OVER FEED AND MILK MARKETING COSTS PER DAY OF ADMINISTRATION OF bGH[a] (\$)

	12.8% Response		25.6% Response	
	Normal Intake	Enhanced Intake	Normal Intake	Enhanced Intake
Base[b]	0.69	0.75	1.28	1.60
Base, with MMG insteadof MML	0.70	0.72	1.22	1.52
Base, with all MML hay instead of half and half	0.75	0.80	1.42	1.71
Base, with 13,000 instead of 16,000	0.60	-.--	1.18	-.--

[a] Increase in return over feed and marketing costs compared to no bGH divided by 215 days of response to bGH.

[b] 16,000 pounds production without bGH using half MML hay and half corn silage.

Table 3

REPRESENTATIVE FARM CHANGES DUE TO bGH RESPONSE WITH 16,000 POUNDS BASE PRODUCTION AND THE ENHANCED INTAKE ASSUMPTION

	12.8% Response			25.6% Response		
	Forage Only	Corn Grain	Crop Sales	Forage Only	Corn Grain	Crop Sales
Increase in ROVC[a]						
Farm, ($)	9,843	15,934	17,142	21,385	34,708	37,672
Per Cow, ($)	153	159	171	329	347	377
Marginal Feed Cost ($/cwt),	5.13	4.82	4.22	4.66	4.22	3.49
Change in Crop Acres (%)						
Hay	-3	+9	+89	-3	+36	+93
Corn Silage	+3	+6	-62	+3	-11	-62
Corn Grain	--	-14	-27	--	-25	-31
Net Purchased Feed[b]						
Change ($)	+6,562	+10,133	+14,517	+12,263	+19,453	+20,628
Change (%)	+30.4	+39.2	--[c]	+56.8	+75.2	--[c]

[a] Return over variable costs.
[b] Feed purchases minus crop sales.
[c] Reduction in excess cash crop sales over feed purchases.

FIGURE 1. IMPACTS OF MILK MARKET PRICES ON RETURN OVER VARIABLE COSTS AND FARM RETURNS FOR REPRESENTATIVE FARMS AT 19.2 PERCENT bGH PRODUCTION RESPONSE (13, 000 Base Production)

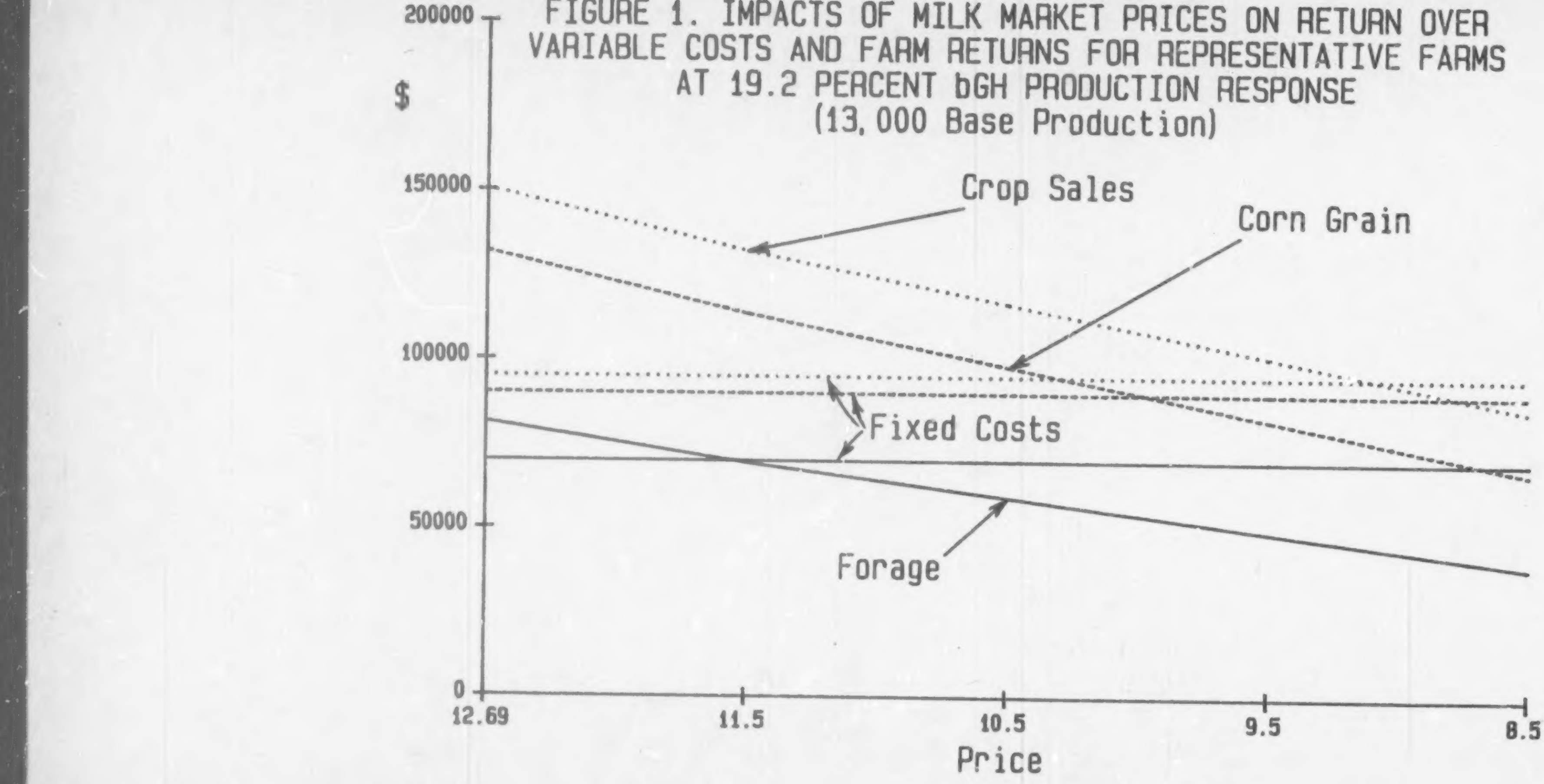
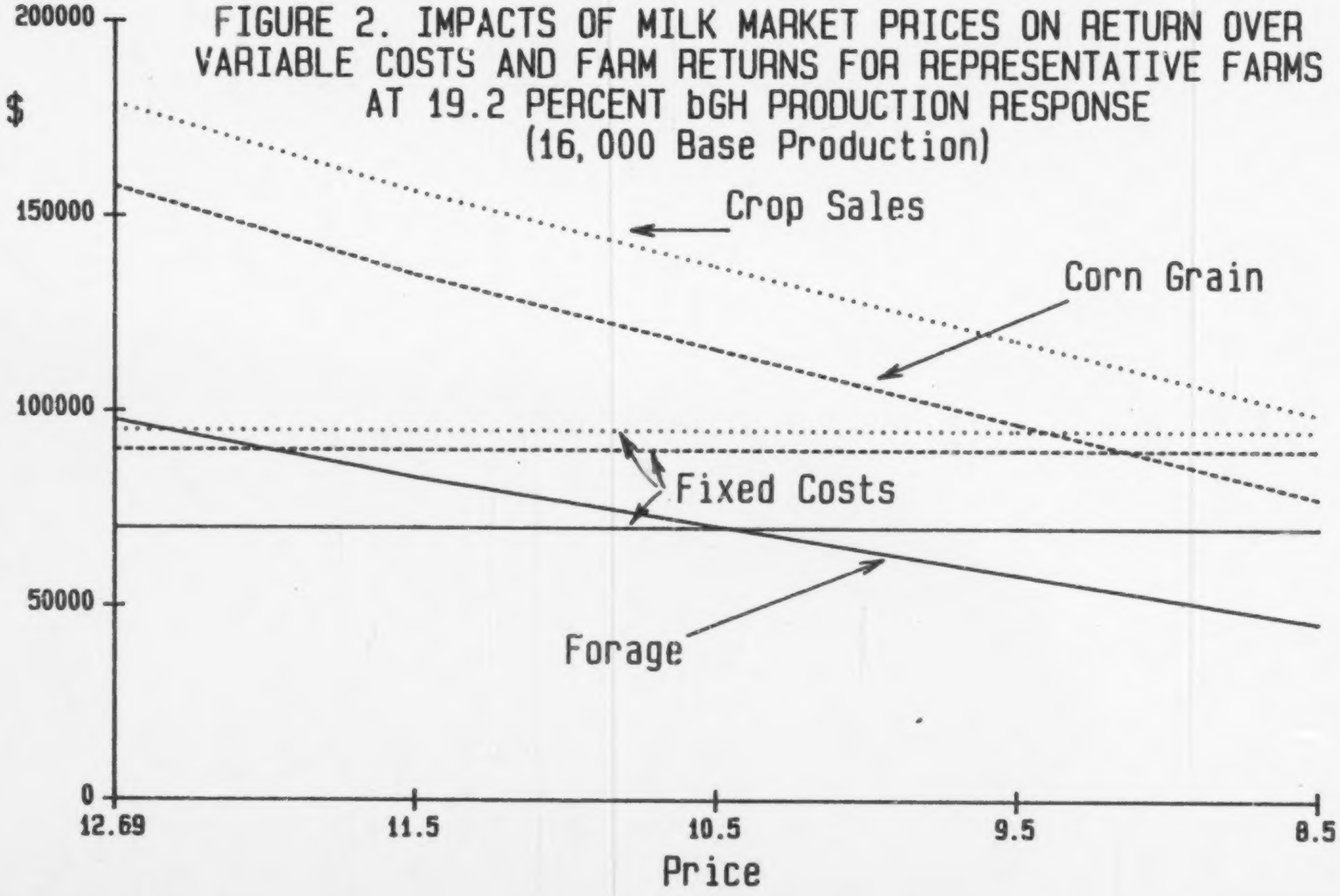


FIGURE 2. IMPACTS OF MILK MARKET PRICES ON RETURN OVER VARIABLE COSTS AND FARM RETURNS FOR REPRESENTATIVE FARMS AT 19.2 PERCENT bGH PRODUCTION RESPONSE (16, 000 Base Production)



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EDUCATION

Degrees	University Attended	Major
B.S. (1962)	University of Wisconsin	Agricultural Economics
M.S. (1964)	University of Wisconsin	Resource Economics
Ph.D. (1966)	University of Wisconsin	Resource Economics
		Minor: Law

PROFESSIONAL EXPERIENCE

Chairman, Department of Agricultural Economics, Cornell University, April 1985-present.

Professor of Resource Economics, Department of Agricultural Economics, Cornell University, 1976-present.

Responsibilities in Research, Teaching and Extension.

Director, Leasing Policy Development Office, U.S. Department of Energy, 1977-79.

Founder and first Director of a 38 position office designed to execute DOE's responsibilities for leasing federal lands (including economic policy, planning and regulations pertaining to economic and production issues). In addition to overall management of the Office, the following responsibilities were assigned:

- Executive Secretary Leasing Liaison Committee,
- Chairman of DOE's Wilderness Land Withdrawal Committee,
- Director of DOE's Coastal Zone Management activities,
- Congressional Testimony and Public Speaking (Numerous),
- DOE's Representative to the OCS Advisory Committee.

Awarded DOE's first Meritorious Service Award (June 1979).

Member Federal Senior Executive Service (ES-5).

Economist, Office of the Secretary, Department of the Interior, July 1972-June 1973.

Associate Professor of Resource Economics, Department of Agricultural Economics, Cornell University, 1971-76.

Assistant Professor of Resource Economics, Department of Agricultural Economics, Cornell University, 1966-71.

University of Wisconsin Fellow, Department of Agricultural Economics, 1964-65.

Teaching Assistant, University of Wisconsin, 1963-64.

Research Assistant, University of Wisconsin, 1962-63.

PROFESSIONAL SOCIETIES

Member, American Economic Association.

Member, American Agricultural Economics Association.

Associate Editor: *Jounal of Leisure Research*, 1971-73.

Mr. **Brown**. I think we'd like to hear from Dr. Kidd first. And again—you have a slide show, too, Dr. Kidd?

Mr. **Kidd**. Yes. Make it short here.

[Slide]

Essentially I'd like to address the question of what happens to the people that go out of business or that feel that they can't continue in business, as well as those that are highly productive and become targets of acquisition.

And I work for a small firm in Milwaukee, L. William Teweles & Co. We do three things: we write large multiclient studies on crop agriculture, usually under the auspices of multinational corporations; we then prepare strategic plans; and then, in turn, we're asked to stick around and buy companies to implement those plans. And we've worked for a list of rather small operations in the past. We're working for Hoechst right now trying to buy a substantial company. We've worked for the USDA in a variety of functions. We've bought two companies for Monsanto. We currently are buying a company for Mitsubishi. And we've worked for Royal Dutch Shell in their acquisition of Nickersons in England. We also helped Genentech with their nonstrategy in agriculture. They really aren't crop people and they should stay the hell away from it. And they've done a very good job of doing that. And 97 more companies over the past dozen years.

[Slide]

Now, there are three technologies that we essentially see will dislocate the ag sector, the crop sector: Plant tissue culture, which was probably discussed yesterday in some detail; transformation or recombinant DNA; and the third technology involves the hybridization of crops via a set of chemicals known as pollen-suppression chemicals. And essentially all of these technologies will be delivered via hybrid seed.

[Slide]

Seed is the widget, essentially, of the genetic engineering, the plant biotechnology companies.

Hybrid seed is really a very good thing to be in these days because it not only delivers a substantial yield increase over varietal seed, it's an annual purchase item—the farmer grows corn, goes back every year and buys his seed—it also bears a very high gross profit margin, 50 percent or better as compared to varietal seed which hovers down around 15 or 20 percent; and finally, there's a proprietary position for industry because the parental lines for the hybrid are kept in our pockets and away from everybody else.

[Slide]

Now, essentially I want to talk about two developments that have been the coupling between the seed industry and the plant biotechnology industry that I think are very, very important and really give you a flavor for what we see going on out there. And the bottom line is that I'd like to address the question on rhizobial inoculants. The USDA doesn't have to do anything. The rhizobial inoculants can be introduced, multiplied and sold without the USDA's blessing. And I think we're going to see over and over again in the examples that I give that this technology and, in turn, the delivery system for the technology, namely, seed, is being predominantly held under wraps by multinational corporations.

[Slide]

Couple of examples I'd like to give you. One example on corn involving the development of corn root worm resistance. If you've ever walked through the fields after there's been a wet spring in the Midwest, you see this. Even despite the fact that FMC can sell $280 million a year worth of Furadan, we still have substantial damage via corn root worm.

[Slide]

Now, if you want to look for corn root worm resistance, you don't look at corn; it doesn't have it. You go down to Texas and you look at sorghum because nobody has ever seen a corn root worm eat on a sorghum plant, and it's because of this mechanism. Sorghum contains a compound known as dhurrin in the roots, not in the shoots or in the leaves. And a simple enzymatic conversion converts dhurrin into cyanogen and glucosides, so when a corn root worm bites into the root of a sorghum plant he ingests two things: glucose and cyanide. And the cyanide sort of slows him down, and it really decreases his sex appetite, he really doesn't want to go any further. [Laughter.]

Now, the idea is that conventional plant breeders are now looking for dhurrin-type compounds in corn, and at the same time the genetic engineers are looking for ways to put genes into corn plants that have cyanogenic ability; in other words, those genes that convert dhurrin into cyanogen and glucosides. The bottom line is that if we have incorporated into seed the ability to resist corn root worm, we increase the value of seed by approximately $60 million in the U.S., whoever has that trait available to them in a proprietary inbred. We cut FMC out of business, essentially.

[Slide]

Now, a lot of people have asked me to distill my thoughts about what's going to happen to corn, so I've taken the artistic license and drawn what the corn plant in the year 2000 will look like. On the right there you see it. It's about one-third shorter than the typical corn plant you see in the Midwest. It's laden with ears. There are two or three ears per plant as opposed to one ear per plant. And you also notice, that there's an increase in stalk diameter and root mass because all of that ear and silage above ground will make the plant top heavy.

At the same time you will notice that the leaves of the corn plant of the year 2000 are upright. That will enable us to pack more corn plants per acre. Right now in Illinois there are 23,000 corn plants in every acre in the field; by the year 1990, that will probably increase to about 30,000 plants or 32,000 plants per acre because of this upright leaf tendency.

You will also see that the genetic engineers will have their way, and they will be able to contribute some fertilizer utilization efficiencies, some disease and frost tolerances, et cetera.

[Slide.]

The second example that I would like to give you that is here and now and not as speculative as corn root worm resistance in corn is the development of high solids in tomatoes. And this is the tail-end of a Hunt Wesson processing plant where they're skimming off the seed and selling the pulp to us in the form of Hunt's tomato paste.

[Slide.]

It's a very interesting phenomenon that the stuff we buy in the can is really devoid pretty much of water and is only solids. "Solids" is the key word in not only the tomato industry, but also in the potato industry and the banana industry. It's the stuff that we eat.

Now, the processer is much smarter than we are. The processer only pays for solids. We're very stupid. I go to the market to buy tomatoes, I buy 95 percent water. And I pay $2 a pound, and I love it. The solids content is the only thing the processer desires. A tomato is about 5 percent solids now. It turns out that the U.S. processing tomato industry, the value of those solids is $385 million. And if we consider that a processing tomato is 5 percent solids, then a 1 percent solids value to the industry is worth damn near $80 million.

Now, if we were a seedsman and we were able to deliver a tomato that has increased in its solid content from 5 percent to 6 percent, we're essentially selling seed now at $30.38 per acre, that would skyrocket up to almost $70. Now, the gross profit margin for people involved in the industry that I love—the seed industry—would go up almost 30 percent.

Now, this sort of example is not original with me. I see Arco and Heinz falling in bed to not achieve 6 percent solids content, but 10 percent solids content. I see DNA plant technology in a New Jersey-based company and Campbell Soup do exactly the same thing. So, essentially what we're going to do is we're going to be enhancing the solids base of the plant and the number of acres planted into processing tomatoes is going to contract proportionally.

[Slide.]

People have also asked me what does the processing tomato, the tomato of the year 2000, look like, and I'm sorry to say it's fairly ugly. It's relatively square because the idea of having a square processing tomato is very good. If you've ever seen car boys processing tomatoes in California, you know the tomatoes at the bottom have to be square in order not to be squished and to make it to the plant in some intact way. As you can see, there are fewer seeds, a lot more meat, a lot more solids. It's candy apple red in color. Right now you get catsup that's red by blending green tomatoes, yellow tomatoes, and blood-red tomatoes. They want all of the tomatoes to be one specific color type. It will probably be an F1 hybrid seed because there will be a lot of people wanting proprietary positions in processing tomatoes. And it will probably have a very high acid content because really the only thing that's left of a processing tomato after it's been mashed up is the acids, and the acids are the things that give processing tomatoes flavor, that make Hunt's tomato sauce so appealing.

[Slide.]

All in all the new plant genetics shortly after the year 2000 will add about $18 billion to the crop value in industrialized countries and in crops that are predominant in those countries.

[Slide.]

Also, if we take a look at the seed that has been genetically engineered, we expect about a third of the seeds sold in the world to contain a trait that has been put into it by one of the three technologies that I mentioned previously. The value of that seed shortly after the year 2000 will be about $12 billion. The commercial seed trade now, the global seed trade is valued at around $36 billion.

[Slide.]

Now, here is where I make my living. Trying to figure out how technology companies and seed companies can become integrated into multinational corporations.

[Slide.]

Essentially, we see that historically the seed industry has been a family-owned type of industry, an extension of farming by and large. They've been privately held companies, very closely held companies, but since the late 1960's more than 90 companies have been absorbed into multinational corporations.

[Slide.]

There have been two waves of merger and acquisition in the industry. One wave starting about 1965, really, when most of the multinational corporations entered the seed business because of pure Malthusian reasons. They saw that the profitability of the industry was very similar to their own. They saw that there were going to be a lot of hungry mouths in the world and that by somehow controlling seed they might be able to get a hold on the food chain that would allow them to control the distribution of food. And finally, if you remember, most of those characters were under attack by environmentalists, and they wanted to really be seen as doing something green for earth. Modifying seed and selling it seemed to be the right thing to do.

[Slide.]

Now, those sorts of reasons propel these characters into the act. We saw Royal Dutch Shell buy Nickerson. We saw Ciba Geigy buy the fourth largest hybrid seed corn operation in the United States, Funk Seed International. We saw Sandoz garble up Northrop King. We saw Pfizer take Trojan Seed, which is a soybean and corn seed operation. And Pfizer so changed the structure and the profitability of Trojan, they so damaged it that to buy a company and do what Pfizer did to it is now known as "Pfizerizing" a company.

Also, we saw Jakes be bought by Rohrer Amchem. Jakes is one of the few companies that we've had the honor of selling 4½ times. We sold it from Rohrer Amchem to Union Carbide, and eventually from Union Carbide into Agrigenetics, along the way we almost sold it to Central Soya but it never closed—that's the half—and eventually Agrigenetics bought it from Union, and then Agrigenetics about 2 months ago we sold to Lubrizol Corp. in Cleveland. And then the granddaddy of all acquisitions that got this whole thing kicked off in the mid-1960's, Upjohn bought the very profitable soybean and vegetable seed operation known as Asgrow.

Now, starting about the mid-1970's there began to be another set of reasons why multinationals invaded this industry. They saw the potential of the genetics coming in. They also saw—they also acted on the basis that other multinational corporations might know something that they didn't know—a little monkey see, a little monkey do. And so they bought into the industry simply because their neighbors had bought into the industry. And finally, they were convinced that seed is really the primary delivery system for the science.

[Slide.]

So, more recently we've had a new set of players. Lafarge Kopay, we closed the deal where they bought Harris & Moran out in California about 6 weeks ago. They also purchased a hybrid seed corn operation in western Iowa known as Wilson's. Now, Lafarge Kopay is the largest cement producer in France. And if you think the farm economy is bad, you ought to see the prognosis for construction in France. It's very, very poor. So Lafarge really thinks it's getting into a growth business—and it is—by participating in the industry and seeing what the genetics can do to the profitability of seed.

Lubrizol, as I said, recently purchased Agrigenetics. That closed within the last 90 days. They also prior to their Agrigenetics position owned Sigco, which is a reputable sunflower seed operation in Minnesota. ICI invaded the U.S. and bought the 16,000-acre Garst Brothers operation about 60 days ago. Ciba Geigy bought half of Ring Around Products, which is based in Dallas, TX. The other half we sold to Rohm & Haas. And Rohm & Haas, also, with its very aggressive strategy in hybrid wheat seed decided to pick up half of the German company—German-based company known as Cokers.

So, I would like to stop right there and give you a chance to ask questions. Thank you for being attentive. (See Appendix E, p. 356.)

[The prepared statement and slides of Mr. Kidd follows:]

PREPARED STATEMENT OF GEORGE H. KIDD

Introduction

To increase crop productivity, four important inputs have been given major attention - water, fertilizer, pest control, and crop variety. Each of these inputs have spawned major businesses. The first three, water, fertilizer, and pest control relate to providing a better environment in which to grow the crop. The fourth, the crop variety, relates to the inherent ability of the plant to be productive within the environment provided. In other words, greater production will result by providing a better environment for crop growth and by improving the heredity of the crop.

Improving the heredity of a crop is accomplished by breeding. Hereditary improvements in crop varieties can be made by three different technologies.

- Conventional plant breeding.
- Plant tissue culture.
- Recombinant DNA.

The latter two constitute technologies termed the "new plant genetics". The methods, objectives, and potential contributions of conventional plant breeding, plant tissue culture, and recombinant DNA to crop productivity are extensively explained and reviewed in this volume and elsewhere.

Data presented in this manuscript is derived from a three-year, in-depth study of the impacts of genetic manipulation on 28 key crops. This 760-page multi-client report, entitled The New Plant Genetics, was conducted by L. William Teweles & Co. under the auspices of over 25 multi-national corporations. Information for the Study was collected through interviews with more than 400 agricultural, scientific, and agribusiness experts from 20 countries and through computer-assisted and manual literature reviews.

Here we quantify the value that new plant genetics will add to crops and seed globally, by the year 2000 and beyond. We also note changes the new plant genetics will impose on the structure of the global seed industry.

Current Macroeconomics of The Global Seed Trade

In 1985, the value of all seed planted worldwide is estimated to exceed U.S. $51 billion. However, only 63% (U.S. $32 billion) of all seed planted is commercially supplied by companies and organizations formally engaged in the research, production, conditioning, and marketing of seed. Commercially supplied seed excludes (a) the grain farmers save from a previous crop for future plantings and (b) seed passed directly from farmer-to-farmer.

The global market for seed commercially supplied is segmented as follows:

Economy	Global Commercial Seed Trade
Developed or Free Market Economies (U.S., Western Europe, Canada, Australia, Japan, etc.)	43%
Developing Market Economies (Africa, ASEAN, South America, etc.)	12%
Centrally Planned Economies (U.S.S.R., Eastern Europe, etc.)	45%

Commercially supplied seed has accounted for an increasing proportion of seed planted in practically every country worldwide. Between 1979 and 1985, the size of the global commercial seed trade grew by 34%. Farmers are increasingly aware of the improved performance resulting from commercially supplied seed. Compared with farm-saved seed, commercial seed assures higher varietal purity, and higher mechanical quality (i.e., germination and cleanliness from weed seed, foreign matter, and damaged seed). All of these factors contribute to improved field performance and increased crop yield.

Several important factors influence the extent of use of commercially supplied seed:

- Farmer education/progressiveness.
- Extension activities, and other public and private sector promotion of commercially supplied seed.
- Seed industry capacity and infrastructure, i.e., production, processing, storage, distribution.
- Commercial infrastructure (e.g., transportation, communications, finance).
- Government policies.
- Economic situation.

The global commercial seed trade is dominated by hybrid seed corn. The size of the commercial hybrid seed corn market has grown almost 25% from 1979-1985. The retail market value is currently approaching $5 billion.

Seed as a Growth Industry

A number of identifiable factors have spurred interest in the seed industry by both multi-nationals and small, high technology research firms. Many of these factors are inter-related.

Technology Outlet. Seed is the delivery system for the new plant genetic technologies of recombinant DNA and plant tissue culture. Plant genetics is an integral part of hybrid seed production using chemical agents because parents of the hybrid must respond to the chemical and still combine to produce increased yield.

A Growth Market. Both domestically and internationally, the volume and dollar value of seed sown is growing annually. For example, the U.S. seed consumption value alone increased by almost 30% from 1982 to 1985. This phenomenon is due to high levels of genetic technology, proprietary varieties, plant variety protection legislation, increases in grass- and grain-fed livestock, and the progressive acreage increase of large volume crops, such as wheat and soybeans.

An International Business. Internationally, the increase in world population and affluence has increased expectations and appetites for beef and other foodstuffs. This, in turn, has put pressure on breeding, multiplication and sale of high performance seed to produce the additional crops. Seed trade leaders believe this growth will continue for the foreseeable future.

For multi-national corporations, seed lends itself to worldwide commercialization. The U.S. is considered the principal world source of genetic development. The successful international operations of present industry leaders lends credibility to the potential for worldwide seed organizations.

Minimal Regulation. Government regulations of commercial seeds are not excessively burdensome. They can, in fact, be considered constructive. Contrasted with food, pesticide, and pharmaceutical FDA and EPA regulations, seed is now relatively regulation-free. Seed research, multiplication, conditioning and marketing decisions are based upon good business judgement, and meeting reasonable regulatory requirements.

Seed is Ecology Plus. Unlike many pesticides which are under attach by environmentalists, seed and the plant sciences are considered ecologically positive. The threat of withdrawal and/or recall because of politically-inspired pressures is unlikely with seed.

Protection for Innovation. Because of the built-in protection of hybrids, the Plant Variety Protection Act of 1970 in the U.S., and Breeders Rights in Europe and other parts of the world, improved seed carries protection similar to patents. For this reason, successful commercial innovation has the possibility of substantial rewards for the developer.

Financial Strength. Other than the majors, much of the fragmented seed industry lacks the financial capability to sustain major research endeavors for breakthrough developments. Long-term marketing strategies of many medium-sized and smaller companies suffer from financial malnutrition. In addition to bringing financial strength to their seed acquisition, Teweles believes that the corporate tradition of professional management, "research patience", and marketing skills could make their seed acquisitions formidable competitors.

Excellent Returns. Based upon the performance of several publicly-held companies, seed industry after-tax return on sales and investment is believed to compare very favorably with those of the food, chemical, and pharmaceutical industries. Contrary to many sectors of the economy, the seed trade has proven to be relatively recession and depression proof.

Timing and Economic Impact of the New Plant Genetics on the Global Seed Trade

Primarily through enhanced yield, the new plant genetics is anticipated to increase crop and seed values. These technologies are expected to add $5.6 billion to the annual value of crops before the year 2000. After 2000, the crop value derived from such genetic improvements will escalate to $20 billion annually (Table 1).

The total retail value of all seed incorporating new plant genetics improvements is expected to increase from an initial $8 million in 1985, to $6.77 billion in the year 2000, and to over $14 billion each year by 2000-2005. This represents a 57% annually compounded growth rate between 1985 and 2000 (Table 1). All figures are in 1983 U.S. dollars.

Eighty-five percent of the commercial impact of new plant genetics on seed is expected in major crops and in advanced countries.

These crops include:

- Wheat
- Corn
- Rice
- Barley
- Sorghum (grain)
- Soybean
- Alfalfa
- Cotton
- Sugarbeet
- Tomato

These crops represent 80% of annual retail seed consumption value in the countries listed below.

The 11 countries include:

- United States
- Canada
- Japan
- Australia
- France
- West Germany
- Denmark
- Holland
- Italy
- Spain
- United Kingdom

These countries represent 90% of annual retail seed consumption value in the developed free world.

A timetable for achievements in the new plant genetics for specific crops is presented in Table 2.

Several research and commercial developments are central to realizing the impact the new plant genetics can have on the seed trade. For example:

Crop/Improvement	Annual Retail Value of Seed Incorporating the Improvement by 2000
Corn with multi-genic resistances to rootworm and borer	U.S. $1,095 million
High-yielding soybeans from effective symbiotic association with Rhizobium	U.S. $1,644 million
Reduction of sugar loss in stored sugarbeets	U.S. $356 million

Increasing Seed Values Using Other Technologies

In addition to the new plant genetics, other technologies, not quantified above, may add considerably to seed values. For instance, hybridization technologies are being developed to economically produce hybrid seed from plant species that have historically set seed after open-pollination. Hybrid seed is an attractive business opportunity because:

- Hybrids typically give farmers 20% - 30% yield increases, compared to comparable varieties.
- Hybrid seed is purchased annually.
- A premium is paid for hybrid seed because it produces a high-yielding crop. Gross profit margins on hybrid cereal seed exceeds 50%, while gross margins on proprietary varietal seed average 30% - 35%.
- Hybrid seed is a proprietary product because the parental lines (inbreds) used to produce the seed are held as trade secrets by their developer. Methods to hybridize crops can also be protected by patents.

Profitable seed businesses have been based on hybrid corn, sunflower, sorghum, and sugarbeets. Many multi-nationals are developing novel chemical and genetic hybridization technologies in hopes of economically producing hybrid wheats, barley, oats, rice, and soybeans.

As for the magnitude of impact, hybrid wheat seed could be a $980 million (1984 U.S. dollars) business in the U.S. by 1995. This assumes that U.S. wheat plantings stay around 87 million acres, that 45% of total wheat acreage is planted in hybrid seed, and that the 47 million units of seed consumed are priced at $21 each. Hybrid wheat seed has been an illusive objective for the past 25 years.

As an aside, we at Teweles are often asked about the economic impacts of the new plant genetics on delivery systems other than seed. The micropropagation of plant and production of transplants by plant tissue culture are limited alternatives to seed. The size of the market for micropropagated plants is small in comparison to that for seed. Currently, the worldwide micropropagation industry is believed to have annual production of about 60 million plants, valued at $20-$25 million at retail. The annual output of the industry worldwide is expected to increase ten-fold by the year 2000. Future growth in demand for micropropagated plants will be in ornamental shrubs, some forest and fruit trees, and high-value, herbaceous trees (e.g., oil palm, coconut, date palm, banana).

Table 1

THE NEW PLANT GENETICS
WILL ADD SIGNIFICANT VALUE TO BOTH CROPS AND SEED

Year	Value Added to Crops Globally[1] (Billions, U.S. $)	Retail Value of All Seed Improved With New Plant Genetics (Billions, U.S. $)
1985	-	0.008
1990	-	0.19
1995	less than 1.0	2.1
2000	5.6	6.8
2005	20.0	14.2

All figures are 1983 U.S. dollars.

[1] The value of all crops worldwide in 1982 was U.S. $124 billion. This value is used as a basis for projections.

Table A-1

GENETIC RESEARCH TIMETABLE FOR KEY CROPS

	Identification, Duplication and Modification of Agriculturally Important Genes	Routine Growth of Plant Tissue In Laboratory Culture Conditions	Growth of First Genetically Transformed Whole Plant	First Plants Altered by New Technology Available to Breeder for Commercial Production	Growth of Transformed Plants on a Routine Basis
Major Cereals					
Corn	now (zein, early maturity genes)	now	early 1990s	now	mid-1990s
Wheat	1985-1987	now	early 1990s	1984-1986	mid-1990s
Rice	1985-1987	now	late 1980s	now	early 1990s
Barley	now (hordein, powdery mildew resistance genes)	now	1986-1988	1985-1987	early 1990s
Sorghum	1987-1989	1984-1986	early 1990s	1988-1990	mid-1990s
Oil Seeds					
Soybean	now (nitrogen fixation genes)	now	early 1990s	1988-1990	mid-1990s
Oil Palm	1988-1990	now	late 1990s	now	after 2000
Sunflower	1985-1987	1984-1986	now	1984-1986	1986-1988
Oilseed Rape	1984-1986	now	late 1980s	now	early 1990s
Forages					
Alfalfa	1986-1988	now	1985-1987	now	early 1990s
Red Clover	now (nitrogen fixation genes)	now	early 1990s	now	mid-1990s
Vegetables					
Tomatoes	1984-1986	now	1983-1985	now	1986-1988
Lettuce	1985-1987	now	late 1980s	1983-1985	early 1990s
Cucumber	1986-1988	1983-1985	mid-1990s	1985-1987	late 1990s
Onion	1986-1988	1984-1986	early 1990s	1984-1986	mid-1990s
Potato	now	now	1983-1985	now	1986-1988
Carrot	1983-1985	now	1983-1985	now	1986-1988
Beans	now (phaseolin)	1984-1986	1986-1988	1985-1987	early 1990s
Peas	now (vicilin, legumin)	1984-1986	mid-1990s	1985-1987	late 1990s
Brassicas	1983-1985	now	late 1980s	now	early 1990s
Grasses					
Kentucky Bluegrass	late 1980s	1985-1987	mid-1990s	1986-1988	late 1990s
Orchard-grass	late 1980s	1985-1987	mid-1990s	1986-1988	late 1990s
Woody Plants					
Fruit, Nut and Ornamental Trees	mid-1990s	1986-1988	late 1990s	early 1990s	after 2000
Forest Trees	mid-1990s	now	late 1990s	early 1990s	after 2000
Specialty Crops					
Sugarbeets	1985-1987	now	early 1990s	1987-1989	mid-1990s
Sugarcane	1987-1989	now	early 1990s	now	mid-1990s
Cotton	1985-1987	now	early 1990s	1983-1985	mid-1990s
Tobacco	now	now	1983-1985	now	1986-1988

Source: L. William Teweles & Co.

Restructuring the Global Seed Industry

Teweles believes that globally there are at least 50 privately owned seed companies with revenues of $50 million or more. These include:

Agrigenetics (U.S.)
Garst (U.S.)
Claeys-Luck (French)
Royal Sluis (Dutch)
Barenbrug (Dutch)
Nungesser (W. German)
Pioneer Hi-Bred (U.S.)

The next tier would be approximately 150 privately owned seed companies with revenues between U.S. $5 - $20 million. The remaining, 1,200 - 1,500 privately owned seed companies, have revenues of up to U.S. $5 million, with many in the U.S. $1 - $2 million range.

Seed companies with revenues more than $10 million are usually vertically integrated and engage in the four principal seed trade functions of research, production, conditioning, and marketing. The smaller firms typically do not have in-house research. They either buy research from others and/or produce and sell seed of publicly developed varieties.

Fueled by economics of scale in marketing and by the potential advantages conferred by new genetic technologies, consolidation of the seed industry has begun. The base of acquirers is shifting to include not only companies basic in agricultural inputs (e.g., herbicides, fertilizer) but to those diversified in pharmaceuticals, energy, and processed foods. Shortly after the year 2000, it is expected that no more than a dozen global companies will dominate the seed markets.

If aggressive seed strategies remain intact, a list of such global seed concerns might include:

- Royal Dutch/Shell
- Pioneer Hi-Bred
- Ciba-Geigy
- Sandoz

About L. William Teweles & Co.

L. William Teweles & Co. was established in 1972 as management consultants, specializing in the international seed and plant science industries. Teweles has conducted numerous proprietary and multi-client seed and plant science studies and has engaged in proprietary consulting assignments from more than 70 international corporations. To date, Teweles has initiated and assisted in the merger or divestiture of 72 seed and plant science companies worldwide. It is believed this represents more than 80% of these transactions in the past 12 years.

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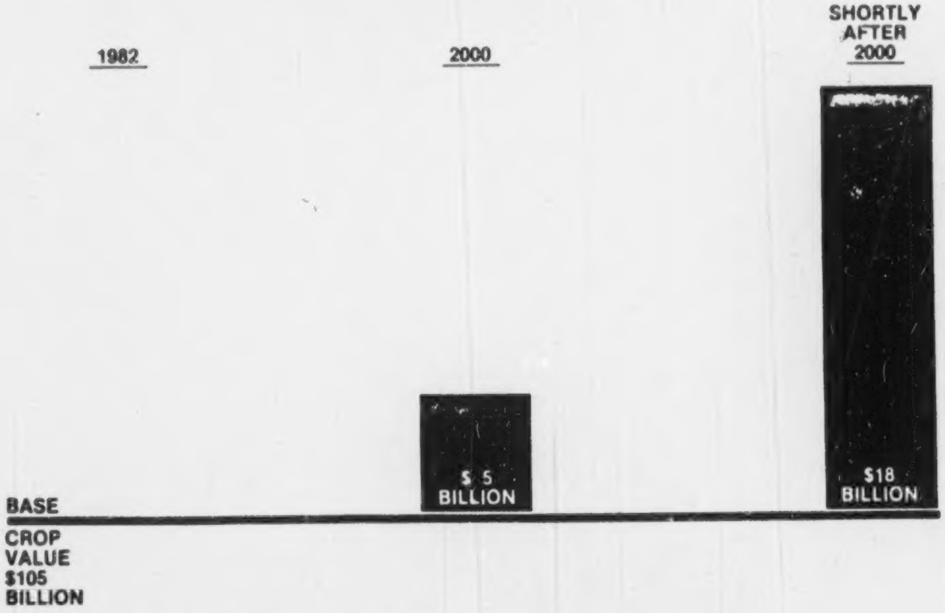
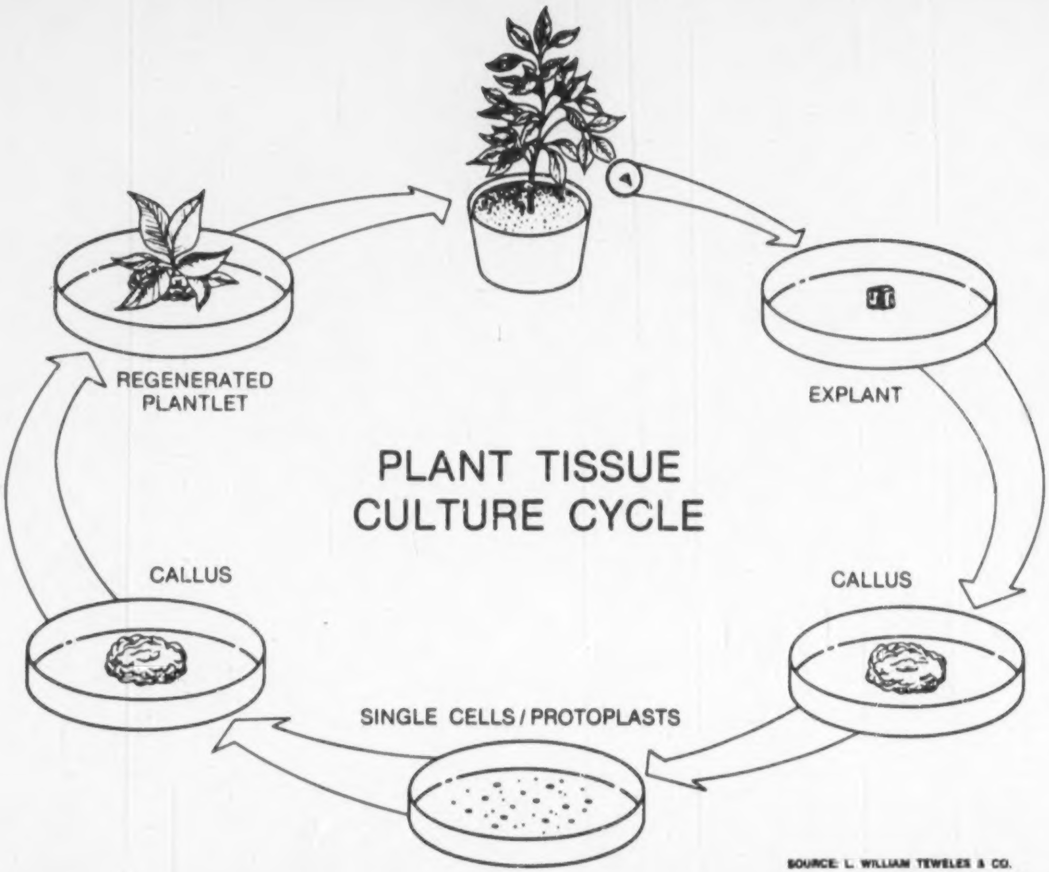
L. WILLIAM TEWELES & CO.

THE NEW PLANT GENETICS STUDY ADDED CROP VALUE*



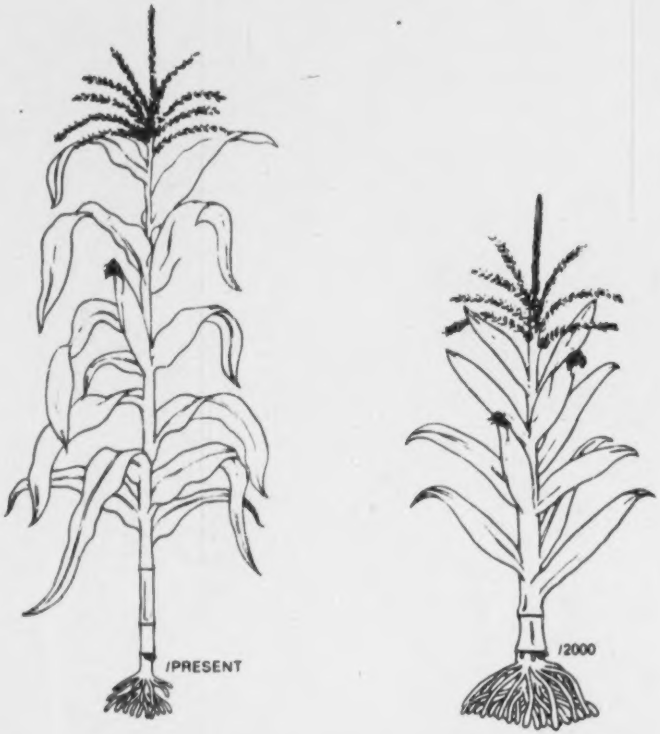
*FOR 10 PRINCIPAL CROPS IN LEADING COUNTRIES

SOURCE: L. WILLIAM TEWELES & CO.
MILWAUKEE, WISCONSIN, U.S.A.



SOURCE: L. WILLIAM TEWELES & CO.
MILWAUKEE, WISCONSIN, U.S.A.

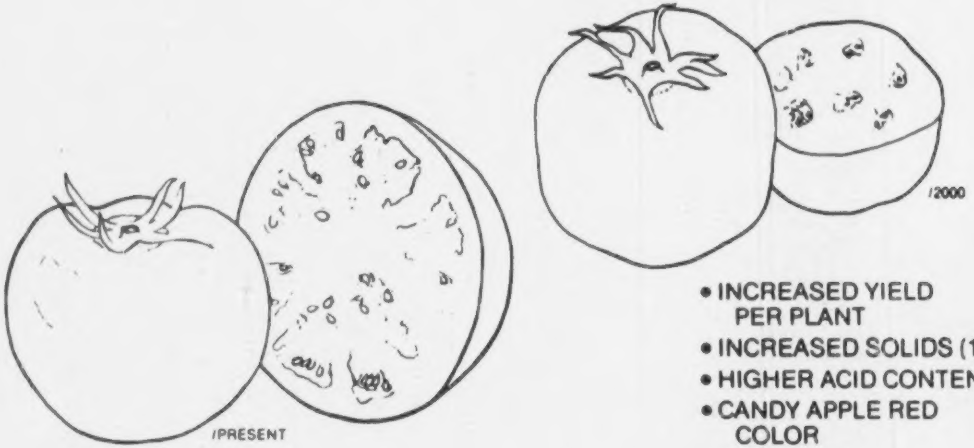
CORN/YEAR 2000



- INCREASED YIELD PER PLANT
- INCREASED PLANTS PER ACRE
- PLANT PRODUCES OWN NITROGEN FERTILIZER
- IMPROVED NUTRITIONAL QUALITY
- HEAT/DROUGHT RESISTANT
- FROST TOLERANT
- INSECT RESISTANT
- HERBICIDE TOLERANT
- DISEASE RESISTANT

SOURCE: L. WILLIAM TEWELES & CO.
MILWAUKEE, WISCONSIN, U.S.A.

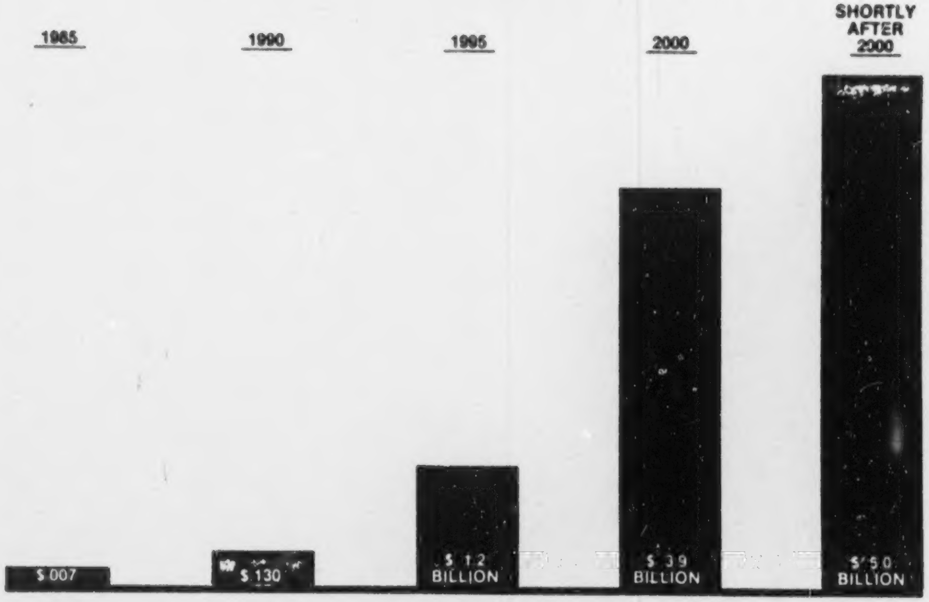
PROCESSING TOMATO/YEAR 2000



- INCREASED YIELD PER PLANT
- INCREASED SOLIDS (10%)
- HIGHER ACID CONTENT
- CANDY APPLE RED COLOR
- F_1 HYBRIDS
- SQUARE SHAPE

SOURCE: L. WILLIAM TEWELES & CO.
MILWAUKEE, WISCONSIN, U.S.A.

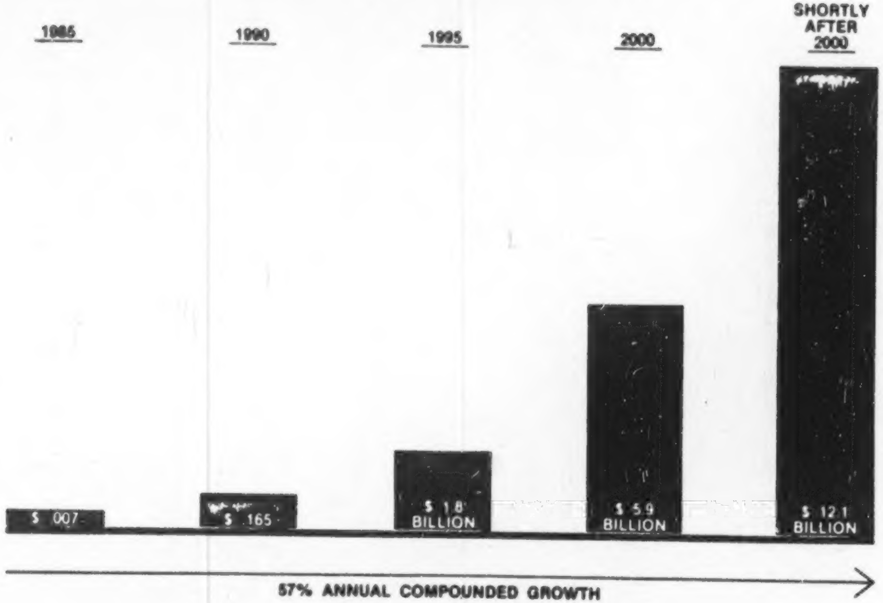
THE NEW PLANT GENETICS STUDY
INCREMENTAL SEED IMPROVEMENTS*



*FOR 10 PRINCIPAL CROPS IN LEADING COUNTRIES; RETAIL SEED VALUE PLANTED EACH YEAR

SOURCE: L. WILLIAM TEWELES & CO.
MILWAUKEE, WISCONSIN, U.S.A.

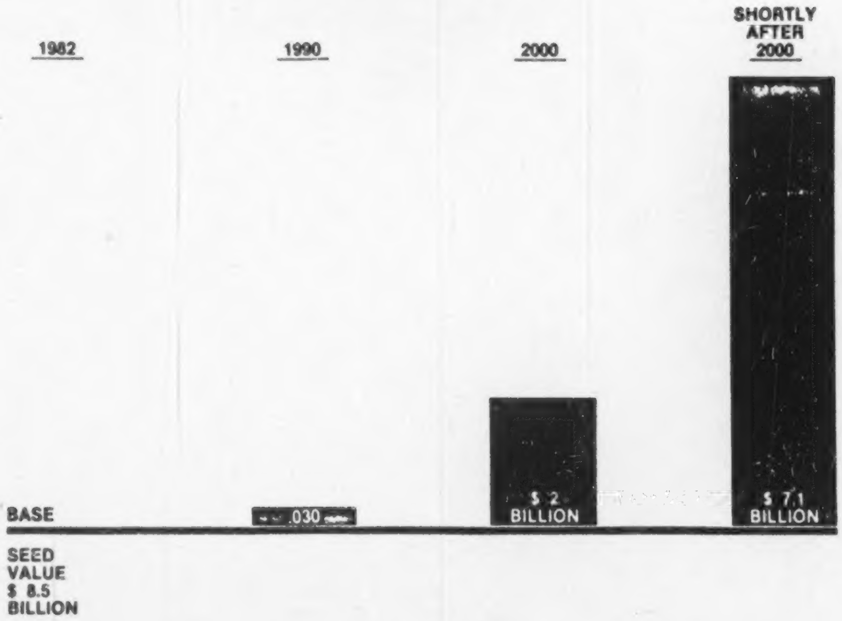
THE NEW PLANT GENETICS STUDY
TOTAL IMPROVED SEED VALUES*



*FOR 10 PRINCIPAL CROPS IN LEADING COUNTRIES; RETAIL SEED VALUE PLANTED EACH YEAR

SOURCE: L. WILLIAM TEWELES & CO.
MILWAUKEE, WISCONSIN, U.S.A.

THE NEW PLANT GENETICS STUDY
VALUE ADDED TO SEED*



*FOR 10 PRINCIPAL CROPS IN LEADING COUNTRIES; RETAIL SEED VALUE PLANTED EACH YEAR

SOURCE: L. WILLIAM TEWELES & CO.
MILWAUKEE, WISCONSIN, U.S.A.

Mr. **Brown**. Mr. Volkmer?

Mr. **Volkmer**. Where will the increased value of the crops and the seeds occur? The United States? Worldwide?

Mr. **Kidd**. Well, there are 11 countries that will get it first between now and the year 2000, and they will be industrialized countries: Australia, Japan, United States, Canada, Western European countries.

Mr. **Volkmer**. What about Brazil/Argentina?

Mr. **Kidd**. Well, Brazil/Argentina not so much because the flow of science has really been stifled to those countries. Now, let me see—let me tell you what I see——

Mr. **Volkmer**. These multinational seed companies——

Mr. **Kidd**. Sure. Exactly.

Mr. **Volkmer** [continuing]. Aren't going to go down there with the best soybean seed they ever had?

Mr. **Kidd**. Yes, well, that's the strategy, but initially they'll try it out in the United States. The other way around in this is the fact that multinational corporations are buying seed companies because they want to deliver technology. Where do they get the technology? They buy genetic engineering firms. And there are 12 genetic engineering firms in North America that specialize in crop modifications. We've sold four of them in the past 6 months. And I'm happy to say, because I feed my kids on this, that I'll probably sell another three this year and next year.

Mr. **Volkmer**. Basically, without a genetic engineering part of the seed business, they're going to be left out, too—

Mr. **Kidd**. Precisely.

Mr. **Volkmer** [continuing]. Just like the small farmer. The dairyman is going to be left out on bovine growth.

Mr. **Kidd**. Precisely.

Mr. **Volkmer**. Is that right?

Mr. **Kidd**. That's precisely it.

Mr. **Volkmer**. So, not all of these people probably are going to last, either?

Mr. **Kidd**. No. I'll say that we envision that by shortly after the year 2000 that there will be about 20 global seed operations that manage not only the distribution of seed, but also are purveyors of science. And some of those guys are already here: Ciba, Royal Dutch Shell, Monsanto, perhaps. You know, we know who most of those guys are.

Mr. **Volkmer**. Well, what is being done in, like in Europe? You know, there are outstanding scientists in Europe just like we got in the United States.

Mr. **Kidd**. Well——

Mr. **Volkmer**. But in this field where are they?

Mr. **Kidd**. The countries have really locked away their equivalence of the U.S. Department of Agriculture. There's really only been one country to try to use a private enterprise to exploit its public innovations, and that's been Britain. Britain formed a company about a year ago, called Agricultural Genetics, and gave them exclusive marketing rights on all of the research done by the British Government in crop improvement. And those guys are really going to town. They recently sold a chunk of their company to Eli Lilly and another chunk to Ciba Geigy, and so the multinationals are really piling in to monopolize the public sector research in Britain.

Mr. Volkmer. OK. Dr. Kalter, I think all of us know about the bovine growth hormone that is coming on, and you gave us some timetables. And not facetiously, and you may not be able to tell me, but there is great concern about—you know, I realize we're going to lose dairy producers because we're not going to need all that much milk. The price is going to go down and displacement is going to happen. But I'm just wondering where it's going to happen.

In other words, if you have a, and we know where most of the major herds are; they're between Florida and the Southwest and California, the large herds. And are we going to start moving milk around in trucks or some other ways and not produce at other places?

Mr. Kalter. It's an interesting question and it's one that's been speculated on quite a bit recently in the press because of a recently released OTA report——

Mr. Volkmer. Right.

Mr. Kalter [continuing]. Which seems to imply, at least the press reports of it seem to imply that production will move from the traditional areas of the lake States to California and the Southwest and Florida. If you carefully read the report, it's a little hard to see where the press reports glean that particular conclusion. However, if you talk to the authors of those particular segments, it's apparent that a mistake was made in the assumptions they used in writing the report.

The report does explicitly say that growth hormone will provide an increase in milk production, with no increase in feed for the animal. And obviously, if that were to be the case, we would expect a comparative advantage shift to the Southwest and California. But that is clearly not the case. And the reason that that assumption was made is because they took the journal articles from the early trials of BGH, which tended to be 5- and 10-day long trials. And it turns out that, although the milk production increases almost immediately, the feed intake does not increase for about—until about 10 days in, and so the early short-term trials gave a miscue as to what would happen with the feed.

Now, Cornell has got the only publicly published, as I understand it, long-term trials. That took place last year. And those articles are referenced, several articles on those trials are referenced, in my submitted testimony by Dr. Bauman, and it's very clear that we have to increase feed intake in proportion to the increase in milk production. Therefore, my conclusion to your question is that I don't think we're going to see the comparative advantage shift between regions that the OTA report would have led you to believe. The animal, the dairy cow in this case, is still a ruminant, and in fact, this particular product actually enhances the fact that we need more hay. And so, I think, that the Lake States are going to be in a very good comparative advantage position vis-a-vis California and Arizona.

Now, that's not to say that there's not going to be some shifts at the margin. I think personally, however, that the major shifts we're going to see are going to be more intra than interregional.

And let me give you a local example. In New York, northern New York, with its short growing season and sometimes poorly drained soil resources, is a difficult area to grow corn grain in some cases. And so those acreages will be disadvantaged compared to western New York, which is quite good corn grain areas. And so, we could very likely in New York see some shifts in production from northern to western New York in dairy.

And so, I think, you're going to see that kind of a shift, but not necessarily a major shift between Wisconsin and New York and California.

Mr. VOLKMER. The other possibility is, of course, just speculating some of Dr. Kidd's clients or former clients may end up coming up with some soybeans that are higher in protein, et cetera, and corn the same way, so you actually use less to produce more, too.

Mr. KALTER. As I understand it, some of the tissue culture at work—work being done at Cornell right now has found some corn varieties or changes in corn species that will mature more rapidly, so we might introduce a new biotech-produced product in northern New York, which would, in fact, make it a better corn grain growing region than it is currently. I don't know how promising that is, but, you know, there's some work underway in that area.

Mr. VOLKMER. And then, too, further genetic engineering, whether it's embryo transplant or what, we may end up with a dairy cow that has three lactation periods in a day, or four; then what are you going to do?

Mr. KALTER. Well, there's all kinds of possible changes in management that could take place. Given the increase in production, we may want to keep this animal on milk for a longer period of time than we currently do. Otherwise, we might want to space out the calving interval. That could very easily happen.

One thing that I would like to comment on that's tangential, perhaps, to this main discussion, but I think for policy purposes it's important. It's not just growth hormone that's going to affect milk production in the next year or two. We have now something on the market by Kodak called Iso-Plus, which is being marketed in Michigan, which is a chemical additive to the feed that increases nutrient uptake in the animal. It's not a biotech product. It's a chemical product, which is increasing milk production by 10 percent and, in some herds, at the same time reducing the feed intake by 8 percent. So you have an overall increase in efficiency in those herds of 18 percent. So, somewhere between 10 and 18 percent is going to occur virtually instantly, and that will be on the market nationwide, as I understand it, by fall. At least the marketing plans in New York are slated for September or October, as I understand it.

So, you've got Iso-Plus, then coming shortly thereafter you've got growth hormone, and you've got additional vaccines and embryo transfer—all of which are now moving animal science into a much more productive phase than we've seen in the last 15 or 20 years.

Mr. VOLKMER. Do we need any changes in government policy in regard to biotechnology and enhancement of hybridization of the seeds and changing genetically?

Mr. KIDD. Well, the way you're going now I can guarantee you that, frankly, most people don't care if they test it here or in

Brazil. And if you look at the four examples that were given previously, I can tell you you've already driven one company, one biotechnology company, almost to Canada. Because, essentially, the Canadian Government and the venture capital people are more excited about having that product developed up there and distributed from Canada, and the company really has no reason to stay in the United States. So, you've really driven their product development cycles to another country.

It's not a theoretical thing, it's already happened. And you know, I'll tell you this: most of the multinationals who are involved in genetics they come to us and they say, "Where are the testing outlets for improved material where there's no hassle?" And they don't care if it's Malaysia. Unilever doesn't care if it's in Malaysia or Mexico or Brazil or Kenya or South Africa, you know, as long as they can show an increase in productivity and that can be worked into their marketing program that will allow them to sell agricultural inputs.

Mr. VOLKMER. Well, we've been using inoculants already for some time. None of those have ever been tested——

Mr. KIDD. Precisely.

Mr. VOLKMER [continuing]. By the USDA or EPA, or anybody else.

Mr. KIDD. Well, you know, the inoculant issue, we participated in the purchase of the two leading inoculant companies, a consolidation of the two leading inoculant companies in the United States. A nitrogen company in Milwaukee was purchased by Allied Corp., and Kaylow Laboratories in Kansas City was a consolidation of a number of other small inoculant producers. Now, they together dominate 80 percent of the inoculant market for *Rhizobium* in alfalfa in the United States, and most of it overseas. Because they sell peat moss in bags and vials of bacteria to Brazil, who formulate their own and give it to their soybean producers.

These companies could introduce and test in the public sector an inoculant X, Y, or Z. They really don't owe it to the USDA, or to anybody else, to disclose how that improvement was made. They might do it just to be good and honest guys, but there is really no recommendation that they do so.

Mr. VOLKMER. And they really don't—that is, in deference to, if you heard Dr. Kendrick. They don't do it in order to get it public in order to make it salable, do they?

Mr. KIDD. Not necessarily.

Mr. VOLKMER. You're not necessarily going to come up to USDA, necessarily——

Mr. KIDD. Not necessarily.

Mr. VOLKMER [continuing]. If you want to test in the public sector?

Mr. KIDD. Not necessarily. Most go for USDA trials simply because they're annual, they're hosted, they're unbiased, and the like. But there have been endorsement programs recently by the major inoculant producers and also by the major seed companies that are sort of, you know, like Hollywood stunts, where we have all the farmers and so many farmers in this country endorsing this type of product: Gee, you're their neighbors, why don't you follow on along? So, the personal endorsement approach is also one that's recently taking hold.

Also, you know there are some very creative things you can do at 5:30 in the morning on the radio. And you know there are a lot of ways to get to a consumer.

Mr. **Volkmer**. Thank you.

Mr. **Brown**. Mr. Packard?

Mr. **Packard**. Time is moving on and I'll only ask a couple of simple questions.

Dr. Kalter, what kind of changes—with milk price supports and quotas and other farm regulations, what kind of changes in farm policy do you think the country would have—the Government would have—to make in order to accommodate the changes?

Mr. **Kalter**. I'm not sure I'm the best person to answer that question, Congressman, because I'm not an expert in dairy price support programs or milk marketing orders. But let me just give you a flavor of what some of our modeling at Cornell is showing. And also let me juxtaposition that against what I hear around the rumor mill is what's going to happen in the farm bill or the dairy support program.

I hear the term "11.60" battered around a lot for a support price; 11.60 is a move in the right direction, there is no question about that. If you had a long enough period of time in which the adjustment could take place, 11.60 would probably, given our modeling, work us into an equilibrium position sometime in the future. But, that time in the future is more than 3 years down the road because it is going to take farmers a long period of time to adjust. We don't have that time. And so 11.60 will not get us into equilibrium by 1987 or 1988, when growth hormone hits the market.

Now, what happens after that is really it seems to me a function of what we do with policy between now and then and after that point in time. Prices are going to have to drop further in my estimation for at least a short period of time. Now, those prices aren't going to go down and stay down. They are going to go down, you're going to get an exit, and then they're going back up. But they'll never come back up to the old levels. And nor should they, because we now have a more productive dairy sector, so that operating costs are down. So in order to make the same profit, they would not have to come up as high as they currently are.

But there's going to be a time period, roughly, we think, 3 to 5 years, when the prices will have to come down. Perhaps, if you let the market work its will, no government interference, perhaps as low as $8 a hundredweight. And that's a scary number. The expectation of that number ever being realized, I think, is remote because, clearly, we're just not going to drop all price support programs in dairy. But I think what this says is that we have got, as policymakers, to start thinking about how do we bring this down far enough to get enough exit out of the industry sector to bring us back into equilibrium or close to equilibrium.

Mr. **Packard**. Thank you.

Dr. Kidd, with the projected population growth both, well, worldwide, do you think that the advances in crop production will keep pace? And if so, do you think it will further exacerbate the surplus problem of the United States but not necessarily solve the shortages on a worldwide basis?

Mr. **Kidd**. Well, really it's never been a question of production. It's always been a question of distribution, and also the willingness of our grain trading companies and our negotiators to cut a good deal. So, as far as we can tell, let's take an example, corn. We see that this science, in conjunction with conventional plant breeding and good cultural practices, will continue to push up corn yields at a little better than 1 percent a year between now and the year 2000. That would put the average corn yield in the United States about 135 to 140 bushels an acre, and that's without trying very hard. So, frankly, the production side of it is something that we don't see as a problem. The yield increases are going to come simply because it is a self-fulfilling prophecy.

Most multinationals who send out marketing research teams ask farmers, "What do you want?" And what does the farmer say? Yield. And then you say, "Well, you've got such a surplus?" And they say, "Well, it's a straw man sort of thing because in the years when the prices are low we want yield because we want to stay in business; in the year when the prices are high we want yield because we want to make some money."

So, whether he's—no matter where the price is he wants yield. And unless the parameters change considerably and we start paying for something like quality, which we've never paid for—we've assumed quality is there—then the farmer will continue to demand yield and the genetic engineering industry, the seed industry—the Monsantos and Royal Dutchs of the world—will continue to put their foot down on the gasoline pedal of yield and really approach any technology that can give it to them.

Mr. **Packard**. What changes in regulation would you suggest?

Mr. **Kidd**. Well, I think the point that was made today is key. I had the, I guess the luxury of consulting with EPA for 3 years under TSCA, and the point in fact is that there are too many gray areas in crop production, seed production, in microbial inoculants of the sort where they really don't fit under any act, whatsoever, unless you really change your words around.

And the previous example that was given is the ice-nucleating bacteria, is it a pest or is it considered a pesticide? Well, it's not considered a pesticide, but it is considered a crop protection chemical. So, if you consider the act to cover crop protection chemicals and not just pesticides, then your ice-nucleating bacteria fits very nicely. But I think there are a lot of gray areas like that that really don't have any established law to fall under, any place you can put them.

Mr. **Packard**. Thank you, Mr. Chairman.

Mr. **Brown**. Thank you.

The broader question it seems to me is whether or not we need to have a mechanism to anticipate the results of some of these changes, something that goes beyond the Office of Technology Assessment, and to engage in certain policy planning activities that will allow us to cope with the adjustments that are necessary. The picture you paint in the dairy industry seems to me to be as dramatic as in any sector of agriculture, and the overall social and economic impacts would be comparable to that resulting from the introduction of the mechanical cottonpicker, which produced the greatest internal migration in the history of this country. And that was only 40-odd years ago, 40 or 50 years ago. And we made no effort to anticipate that and to take any remedial action. Of course, you can argue whether we should or not, I don't know. Let the changes fall where they may.

But do you have a feel for whether or not we should take some form of action to ameliorate the problems caused by the dislocation of half the dairy farmers in this country?

Mr. KALTER. Well, I think my testimony argued yes, because, on the one—let me take two parts of your question to me. On the second part, whether we need a program, we obviously need a program it seems to me. We need some kind of a financial stress program.

In New York, we're actively starting to think about what that program should look like. There's the idea now that we do a short-term research project to identify what the characteristics of these farmers are that are going to have to leave the sector to see what we could do about it either looking for alternative enterprises for those individuals or about retraining them for other places in the labor force. And then the second phase of the project, if we undertake it, would be to look at the extension side of this and say, OK, how do we get out to these people? How do we reach these people? And how do we get them involved in some type of a retraining program?

So, I think the answer is absolutely yes, we do need some type of a program. The actual outlines of it I'm not prepared to elucidate on today because I just don't know. I don't think we've done enough research.

The first part of your statement, I've been advocating for 2 years amongst my colleagues and having a very difficult time getting the point across, that we ought to be undertaking more advanced research on what the impacts of this new technology is going to be. Now, we chose growth hormone as a case study at Cornell because it was a near-term product that looked like it was going to have dramatic implications on our State. We are currently looking at other ones. The swine hormone, for example, has got potential which looks almost unbelievable as well and will have dramatic effects on corn land production as a spinoff and things like this.

We do need to begin to study these things in an organized fashion. The economists are not very notorious for being accurate forecasters, and I don't want to imply that what I'm telling you today is going to come true to the last nickel and dime. But I do think the trend that I'm pointing out is going to be there. I think that's what's important for people to look at when they're making policy. And unless we call this to their attention, they're not going to even bring it into their decisionmaking matrix. And so, what we're trying to do—and you may have seen an article that Mr. Sinclair had in the *Washington Post*, concerning our research. What we're trying to do is alert people to the fact that something is going on out there and to try to get them to think about it; and whether it requires changes in Government policy or not, I don't know. In some cases it will, in some cases it won't.

But at least the private decisionmaking apparatus needs to be geared up far enough ahead of time to take account of this and to try to reduce the dislocation effects. I have a great faith in the private sector being able to head this off if they have enough advance knowledge.

Mr. **Brown**. The discussion with regard to the dairy bill does, of course, contemplate moving the support price down to the figures that were mentioned, and also it probably will include a trigger mechanism with regard to the amount of surplus production, which will lower it even further if the surplus goes above a certain trigger point.

There has been a proposal floated to include with that a mechanism for a buyout of those herds which are uneconomical and which the farmer no longer feels that he wishes to compete. And that would be a Government buyout with liquidation of the herd, and so on. I don't know whether it's well enough defined to be able to specify it more accurately than that.

But the thing that bothered me in that connection, and it will probably occur anyway, is liquidation of a large number of dairy cattle is going to have an impact on the beef market, at least temporarily. And it bothered the beef producers a great deal when we were talking about this in connection with the last revisions in the dairy support price. That's another example of economic repercussions, which I presume were not even included in your analysis but which are going to concern us because the beef people have almost as good a lobby as the dairy people. Not quite.

Mr. **Kalter**. I think that could bear some careful study. My experts in our department at Cornell on the beef side argue, at least to me, and I don't have the numbers with me today, but they argue that this may be a relatively minor impact. Because when you compare the national dairy herd to the number of beef animals slaughtered every year, we're not talking about a tremendous increase in slaughtering. You are talking about some increase, and at the margin it's going to have some effect. But you know, we're talking about a relatively short run situation when you do a buyout like this.

I think the thing that would concern me perhaps more is that we just not offer a buyout, but we give these individuals some alternatives. What will they do with their lives from this point on? We might be solving part of an economic problem in one sector and creating a social and economic problem in another sector. And I think we really have got to look at where these individuals are going to go and what they're going to do, and that's part of the research project——

Mr. **Brown**. How many people are we talking about if we were to contemplate, say, loss of half the dairy farm units in the country?

Mr. **Kalter**. Well, I can quote New York, I can't quote the Nation. I believe we have currently roughly 12,000-odd dairy farmers in New York, and so you can take it from there. If you're talking 25 percent of those, we're in the area of 3,000. If you're talking 50, you're in the area of 6,000; over some period of time.

Mr. **Brown**. Yes. I want to ask Dr. Kidd just one additional question, and then I think that we ought to close up shop here.

Periodically, in the past, the question of what—this large scale acquisition of seed companies by the multinationals has come up in connection with what's happening to our germ plasm resource capability. Are we limit—moving in the direction you're talking about here, are we really limiting our germ plasm resource, giving inadequate consideration to maintaining the diversity of that resource so that we'll have the capability to make genetic changes in the future? Have you given that subject any thought?

Mr. KIDD. Oh, yes. One of the first acquisitions—there are usually for most multinationals less than 10 acquisition criteria. And believe it not, most of those acquisition criteria have nothing to do with the profitability of the particular types of companies they may be looking at. They're worried about species. They're worried about marketing and distribution outlets to fit their own existing product base, et cetera.

One of the first things that's fallen out on the list in the last two acquisitions that we've done is germ plasm. They're acquiring these companies because they have good germ plasm bases and because they think they can bring—the multinational can bring science to bear on broadening the germ plasm base. Because let me tell you for Hoechst to spend a few bucks sending 10 people around the world to the tropics and to the highlands of Peru, I mean that's nothing. But for a pioneer or even a healthy Dekalb to do it, that's a significant amount of money.

Mr. BROWN. Yes.

Mr. KIDD. So germ plasm has really become much more of an issue as far as acquisition criteria for these seed operations is concerned.

Mr. BROWN. Well, I don't think most people, and I'm sure that applies to most Congressmen, appreciate the importance of that problem. And we've done relatively little about taking action that would preserve the germ plasm resource. It's at least an optimistic note to know that some of the multinationals are concerned about it.

Mr. KIDD. It's falling into private hands. If the USDA or other agencies decide not to maintain it, I can tell you very well that the people at Ciba and the people at Royal Dutch are not neglecting this at all. You'll never know about it. You'll never see it. And it'll be sold as Hybrid 7248 in western Iowa. But that's about it.

I can tell you that the multinationals are really extremely concerned about acquiring good germ plasm and then making sure that their genetic base, in the species that they're interested in, is diverse.

Mr. BROWN. I recall reading that fascinating article in the *New Yorker* about the history of corn. I don't know whether you read it or not.

Mr. KIDD. Oh, yes.

Mr. BROWN. In which that point was emphasized.

Mr. KIDD. Um hum. Yes.

Mr. BROWN. Well, this has been a fascinating experience. Do you have any further questions, Mr. Volkmer?

Mr. VOLKMER. No, no. It just becomes apparent to me that the structure of animals and plants is just going to change a lot more rapidly in the next 20 years, probably, than in the previous 100 years.

Mr. **Kidd**. Precisely.

Mr. **Volkmer**. Is that a correct statement?

Mr. **Brown**. Faster even than automobiles.

Mr. **Kidd**. Faster than the EPA. [Laughter.]

Mr. **Brown**. Gentlemen, we thank you very much for your contribution.

And the subcommittee will be adjourned.

[Whereupon, at 4:50 p.m., the subcommittee was adjourned, to reconvene, subject to the call of the Chair.]

APPENDIX A

EMERGING BIOTECHNOLOGIES IN AGRICULTURE: ISSUES AND POLICIES

A National Biological Impact Assessment Program
March 1985 Update

Chapter 6

PROGRESS REPORT III
November 1984

Division of Agriculture
Committee on Biotechnology
National Association of State Universities
and Land-Grant Colleges

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Executive Summary

A national program is proposed to assess the biological impact of the release of organisms containing recombinant DNA for agricultural use. This National Biological Impact Assessment Program would be organized using the existing national agricultural research network. It would assure the safe release of recombinant DNA products into the environment through a three-level impact assessment plan using specified criteria and protocols, many of which are already in place in the national agricultural research network. The program builds on the experience and success of the NIH-RAC and the associated Institutional Biosafety and Cultivar Release Committees. However, the National Biological Impact Assessment Program would extend oversight of recombinant DNA research beyond present coverage and would include commercial and non-experimental releases of recombinant DNA products. The proposed program can be integrated with the "Proposed Coordinated Framework for the Regulation of Biotechnology" (Federal Register, December 31, 1984) and complements existing federal regulatory authorities. This report represents a revision of Chapter 6 in the "Emerging Biotechnologies In Agriculture: Issues and Policies" Progress Report III, November 1984, Division of Agriculture Committee on Biotechnology, National Association of State Universities and Land-Grant Colleges.

NATIONAL BIOLOGICAL IMPACT ASSESSMENT PROGRAM

I. Introduction

The agricultural community continuously assesses the impact of plants, animals and microbes within a wide range of cropping and animal production systems. These assessments are made not only to maintain agricultural stability but also to assure the protection and preservation of the environment. Particular care is taken with introductions of new or genetically engineered plants, animals and microbes. Any new material is assessed carefully to determine if it is agriculturally beneficial without threatening the environment. For all major crops each state employs a wide range of protocols in which new forms, varieties, species and biocontrol agents are tested, recommended and appraised continuously for performance during commercial use (See Appendices A and B).

Because of recent scientific advancements there is now the exciting prospect of using biotechnological research techniques to produce genetic improvements previously considered impossible. To insure responsible use of biotechnological products, their biological and environmental impact must be assessed. In order to achieve proper assessment, a National Biological Impact Assessment Program (NBIAP) is proposed. This will ensure that the benefits of biotechnology are not attained at undue expense to the environment. NBIAP is designed to take advantage of the long history and successful experience of the state and federal agricultural research systems. This existing national network of agricultural scientists can serve as both a model and framework for the development of NBIAP. NBIAP will assess the biological impact of plants, animals and microbes produced by genetic engineering research including recombinant DNA (r-DNA) methodologies. NBIAP will function in an open and visible manner. It will assure that the maximum benefits of biotechnological research are gained for agriculture and society while continuously protecting the environment.

The primary function of NBIAP will be to study the effects of r-DNA technology and to assess the possibility of risks to society and the environment. Risks must be evaluated in the context of individual experiments in order to utilize present knowledge most effectively. As knowledge and experience in r-DNA advance, broadly applicable protocols and guidelines will be developed. Analysis of genetic effects will focus on the stability of engineered changes and the possibility that genetic elements might be transferred from one organism to another. Interactions and relationships among organisms must be inspected closely to evaluate the possible consequences of releasing the products of r-DNA technology into the environment. All of the above will be considered by NBIAP in order to assess the effects of research and experimentation with r-DNA in relation to society and the environment.

II. Rationale

This document sets out a plan for an expanded national program to utilize existing scientists, research networks and protocols to assess biological changes in agricultural and related ecosystems. It is urgent to begin now to delineate appropriate and acceptable scientific methods for the assessment of the products of biotechnological research.

It is proposed that NBIAP be established within the United States Department of Agriculture (USDA) and its cooperating state institutions (State Agricultural Experiment Stations and the State Cooperative Extension Service) in order to capture the benefits of existing experience in the most economic and efficient manner. No other agency or organization could offer a comparable structure, geographic distribution of expertise, depth of experience, impartiality of assessment and proven history of scientific accomplishment. Duplication of this network would be both costly and unjustified.

The mission of the NBIAP would be to assess fairly, accurately and continuously the impacts of genetically altered organisms produced by genetic engineering research. This close and continuous scrutiny by a national network of agricultural and allied scientists would enable the United States of America to gain maximum benefit from biotechnological research while assuring the greatest possible protection of society and the environment.

In developing the following sequence for impact assessment by NBIAP, existing state and federal structures were utilized. Additionally, new protocols have been integrated into the established network. The proposal has the advantages of reducing the costs of implementing the program and of placing a significant amount of regulatory and assessment responsibility at the local level as skill and experience are accumulated.

III. History

The United States agricultural research community has long recognized its obligation to evaluate and judge the progress of its activities. The continuing development of new crop cultivars, breeds of livestock and strains of agriculturally related microbes has dictated the need for constant oversight, appraisal and replacement of existing techniques. For example, the release of a single new wheat cultivar may involve as many as ten years of tests at twenty cooperating State Agricultural Experiment Stations (SAES) and thousands of records on performance available in public reports.

The disasterous effects of the gypsy moth, kudzu vine and the Dutch Elm Disease which were introudced by commercial interests are constant reminders of the need for caution. These introductions of organisms into habitats to which they were not native did not have the benefit of the careful scrutiny of the agricultural research community. Research, careful evaluation and oversight must accompany releases of organisms into the environment. The testing and assessment network of the agricultural research community has operated safely and successfully for more than 75 years while releasing new varieties of organisms into the environment.

The size and distribution of the existing national system also speak in its favor. Each year American agricultural scientists test thousands of plant selections, animal breeding lines, microbes and other products of conventional genetic research. Sites throughout this nation, in selected climates, permit examination of genetic materials over a wide variety of conditions. The network permits continuing assessment of products of agricultural research. Many years of experience, procedures and protocols contribute to a strong and dependable national assessment system. This system provides an appropriate framework upon which to build NBIAP. Examples of specific protocols are presented in Appendices A & B.

IV. Coordination of the National Biological Impact Assessment Program with Federal Agencies and Existing Review Structure

It is planned that NBIAP will interact with federal and state agencies as well as private sector interests. In the regulation of biotechnology, NBIAP would work closely with the State Agricultural Experiment Stations (SAES), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the National Science Foundation (NSF) and other appropriate agencies. These interactions will be accommodated by the structure delineated in the Cabinet Council Working Group on Biotechnology (CCWG) "Proposal for a Coordinated Framework for Regulation of Biotechnology" (Federal Register, December 31, 1984, 49 FR 50856), which utilizes Scientific Advisory Committees in the various agencies and an overall Biotechnology Science Board.

The safety, regulation and advantages of laboratory research involving r-DNA molecules have been addressed satisfactorily since 1974 by the multiagency Recombinant DNA Advisory Committee (NIH-RAC), which is sponsored by NIH. The NIH-RAC utilizes the Institutional Biosafety Committee (IBC) system to initiate review of r-DNA research projects. As biotechnological research advances from the laboratory into the external environment, additional safety issues arise. NBIAP will supplement the existing review processes with resources and expertise based on an extensive, national network of agriculturalists.

NBIAP will be coordinated with the IBC system. The IBC's, as currently described in the NIH "Guidelines for Research Involving Recombinant DNA Molecules" (NIH r-DNA) (Guidelines Federal Register, November 23, 1984, 49 FR 46266), must meet the following requirements:

A. Be comprised of no fewer than five members selected for collective knowledge in r-DNA technology and capability to assess the safety of r-DNA research and risk to public health and/or the environment. IBC's are to include persons with knowledge/expertise in r-DNA technology, biological safety, physical containment, institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes and the environment. Membership is to include at least one laboratory technical staff member.

B. At least two members:

   1. Shall not be affiliated with the institution.
   2. Shall represent the public sector and the immediate community broadly with respect to health and protection of the environment.

C. Must include a biological safety officer when research is being conducted at certain containment levels.

Responsibilities of the IBC include review of research projects for compliance with the NIH r-DNA Guidelines, notification of principal investigators with reference to review results, establishment of containment levels, review of institutional r-DNA research to ensure that the NIH r-DNA Guidelines are followed, adoption of emergency plans and notification to proper officials of problems or violations.

For the NBIAP to make optimal use of existing IBC's, persons with appropriate expertise should be added to form an expanded local IBC (EL-IBC) that would be capable of addressing issues pertinent to agriculture and the environment. In view of the "Proposed Coordinated Framework for Regulation of Biotechnology," an EL-IBC could be formed at the institutional level to be responsible for r-DNA guidelines as well as protocols established by NBIAP. The EL-IBC's could be accountable to the proposed Biotechnology Science Board (see Federal Register, December 31, 1984). The Biotechnology Science Board should provide a mechanism to insure EL-IBC compliance. This mechanism might include monitoring of IBC activities, site visits and reviews.

As set forth in the "Proposed Coordinated Framework for Regulation of Biotechnology" (Federal Register, December 31, 1984) FDA, EPA, NSF, NIH and USDA will all incorporate Scientific Advisory Committees (SAC's) within their structures. Each advisory committee will be composed of "members of the scientific community who possess demonstrated, recognized expertise in disciplines related to biotechnology." As defined by the CCWG, the SAC's will provide detailed scientific review of applications for biotechnology projects and issues submitted to them by federal agencies.

The Biotechnology Science Board, as proposed by CCWG, ("Proposal for a Coordinated Framework for Regulation of Biotechnology," Federal Register, December 31, 1984) would act as a parent board chartered by the Department of Health and Human Services. It would report to the Assistant Secretary for Health and would include two members from each agency-based SAC. The CCWG plans that this board will:

A. Receive agency summaries of applications and review (or request review of) specific proposals,
B. Review committee reports,
C. Evaluate review procedures set by SAC's,
D. Conduct analyses of broad scientific issues,
E. Develop generic scientific guidelines and
F. Provide a forum for public concerns.

The organization of the SAC's and the Biotechnology Science Board will provide an adequate mechanism to manage a large number of proposals in all areas of r-DNA technology. The system also allows for the coordination of activities among federal agencies. The NBIAP will supplement this proposed model by supplying protocols to examine the impacts of agricultural r-DNA projects on the environment. Extensive data, sophisticated tools of molecular biology and modern computer technology are all available to NBIAP to assess the impact of specific releases of agricultural significance.

Existing tools will be utilized to establish further criteria and to make decisions based on the best available scientific and other pertinent information available.

NBIAP will also be coordinated with the SAES Cultivar Release System, which has assessed releases of new plant varieties for 75 years. Under this system, all new varieties of plants are studied carefully before they are released for commercial use. New varieties are scrutinized before their release by committees at individual SAES institutions where expertise in the basic sciences of genetics, ecology, physiology, statistics and mathematics are utilized. Interacting among scientific disciplines such as entomology, pathology, soil science, engineering, agronomy, forestry, horticulture, economics, food science and human nutrition is a fundamental part of the SAES Cultivar Release System.

NBIAP would make efficient use of the SAES Cultivar Release System by utilizing its expertise for proposed releases of new varieties (cultivars) of plants containing r-DNA molecules. The local Cultivar Release Committees would expand their expertise in the area of r-DNA where necessary. The Cultivar Release Committees would receive all proposals for releases of new varieties of plants. Criteria would be established for assessing environmental impacts of such releases. The Committees would act on these proposals and forward them to NBIAP for final approval.

It is proposed that laboratory research within the broad scope of food and agriculture be subject to NBIAP oversight. This includes research under special contained conditions (e.g., greenhouses, biotrons, field plots, research plots, etc.). While FDA and EPA regulation activities pertain to commercial products and are generally distinct from the proposed NBIAP mission, NBIAP would provide support for FDA and EPA activities. NBIAP would also provide a research capability for those agencies for the development of additional impact assessment techniques. Thus, NBIAP would support directly the commercial and non-experimental release of r-DNA products that fall within the statutory authority of both EPA and FDA and provide those agencies with a source of research and development that they currently do not possess. Additionally, because of the extensive involvement and expertise of the USDA with plant and animal research and development, it is proposed that all plants and animals that are products of r-DNA research be subject to NBIAP oversight with reference to research as well as commercial development.

The proposed path of approval under NBIAP for applications relating to r-RNA, r-DNA and cell fusion would be:

A. Application to appropriate institutional committees, including EL-IBC's and Cultivar Release Committees.
B. Application to appropriate agency for approval and/or funding.
C. Agency sends application to NBIAP for review.
D. NBIAP reviews application and submits report to:

   1. Agency requesting review.
   2. Biotechnology Science Board for comment.

E. After approval, investigator begins the research project.

This design retains control of r-DNA experimentation. It should maintain the flexibility to allow greater IBC responsibility as knowledge and experience accumulate. The history of NIH-RAC with laboratory r-DNA research oversight has established this process of distributing responsibility where specific knowledge resides. If that pattern is continued, r-DNA research would be reviewed at the national (SAC) level while vesting oversight with the local IBC when proper.

V. The National Biological Impact Assessment Board

As proposed, NBIAP takes maximum advantage of existing structures at both local and national levels. The only new structure proposed is a National Biological Impact Assessment Board (NBIAP Board) appointed by the Secretary of Agriculture for Science and Education. The function of the NBIAP Board will be: (1) to review the process of biological impact assessment on a continuing basis, (2) to act as a governing board for NBIAP and (3) to establish guidelines and protocols, related to the development and release of r-DNA organisms.

It is important that composition of the board include members from the following organizations or groups:

The State Agricultural Experiment Stations
The Cooperative State Research Service
The Agricultural Research Service
The Animal and Plant Health Inspection Service
The Economic Research Service
The Extension Service
The Forest Service
The Department of Interior
The Environmental Protection Agency
The Food and Drug Administration
The National Science Foundation
The National Institutes of Health
Other Federal Agencies
Appropriate private sector groups and organizations.

The Board, in concert with representatives from EL-IBC's of both industrial and academic institutions, would develop criteria to evaluate proposals for r-DNA organism field release experimentation and for commercial and other non-experimental releases of r-DNA organisms into the environment. Additionally, the NBIAP Board would develop an infrastructure of subcommittees to evaluate proposals in an array of program areas. These program subcommittees could be organized into the following categories: cellular and protoplast regeneration of plants, embryo rescue and transfer in plants and animals, the identification of agriculturally important genes, the transfer of agriculturally important genes from one genome to another, the regulation and expression of agriculturally important genes in their new environment, microbes containing r-DNA molecules, plant species containing r-DNA molecules and animal species containing r-DNA molecules.

The NBIAP Board will develop ties with other agencies and organizations as appropriate. For example, close ties would be developed between the NBIAP Board and EPA, NIH, FDA and NSF. The conceptual relationship of NBIAP to other agencies and activities and to the proposed Biotechnology Science Board is shown in Figure 1. This representation is consistent with the "Proposal for a Coordinated Framework for Biotechnology Regulation" (Federal Register, December 31, 1984) that calls for the formation of individual SAC's at FDA, EPA, USDA, NIH and NSF.

Alternatively, Figure 2 shows the relationship of NBIAP to a single, multiagency SAC. Strong arguments have been stated for the formation of such a body, in order to coordinate oversight for all federal agencies more efficiently.

VI. Process of the National Biological Impact Assessment Program

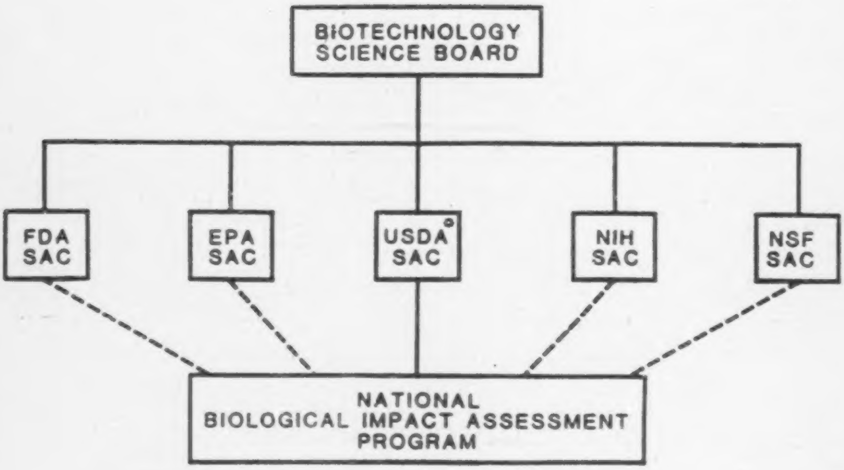
As currently envisioned, NBIAP would function at three levels of r-DNA research and development: 1) laboratory and related containment research, 2) special contained research and 3) commercial and other non-experimental releases. The following sequences are organized to accommodate these levels of inquiry.

Level 1. Laboratory and Related Containment Research

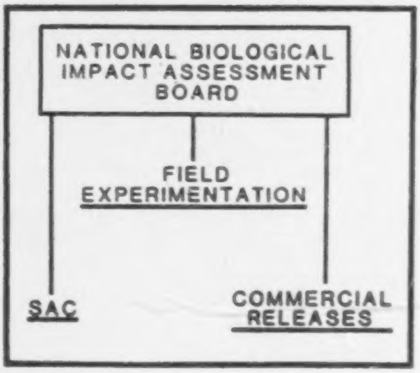
The outline to be followed for approval of laboratory and related containment research consists of existing procedures and protocols. The following sequence is based on the assumption that, as the proposal is submitted to the various local and national organizations, it is approved and then forwarded.

A. Development of the proposal by the principal investigator and/or cooperators.
B. Submission of the proposal to the EL-IBC or SAES Cultivar Release Committee.
C. Submission of the proposal to the appropriate institutional committees on radiation, animal safety, ethics, human review board or other required reviews and obtaining necessary permits required for the transport of a pest or pathogen.
D. Submission of the proposal to the State Agricultural Experiment Station (SAES) Director and/or other appropriate office for review and approval.
E. Submission of the proposal by the institution to the agency from which funding is requested. If the proposal requires federal review, but is not seeking federal funding it would be submitted directly to the NBIAP Board.
F. Submission of the proposal by the funding agency to the NBIAP Board.
G. Return of the proposal to the funding agency by the NBIAP Board.
    Note: The scientific quality and relevance of the research proposal would not be judged by the NBIAP Board, but by the funding agency.
H. Review and return of the proposal to the principal investigator by the funding agency with a statement on action taken including reference to the NBIAP decision. The funding agency may approve the proposal, request additional information or deny it.

ORGANIZATIONAL RELATIONSHIP: NBIAP: OPTION 1


BIOTECHNOLOGY SCIENCE BOARD
FDA SAC
EPA SAC
USDA° SAC
NIH SAC
NSF SAC
NATIONAL BIOLOGICAL IMPACT ASSESSMENT PROGRAM

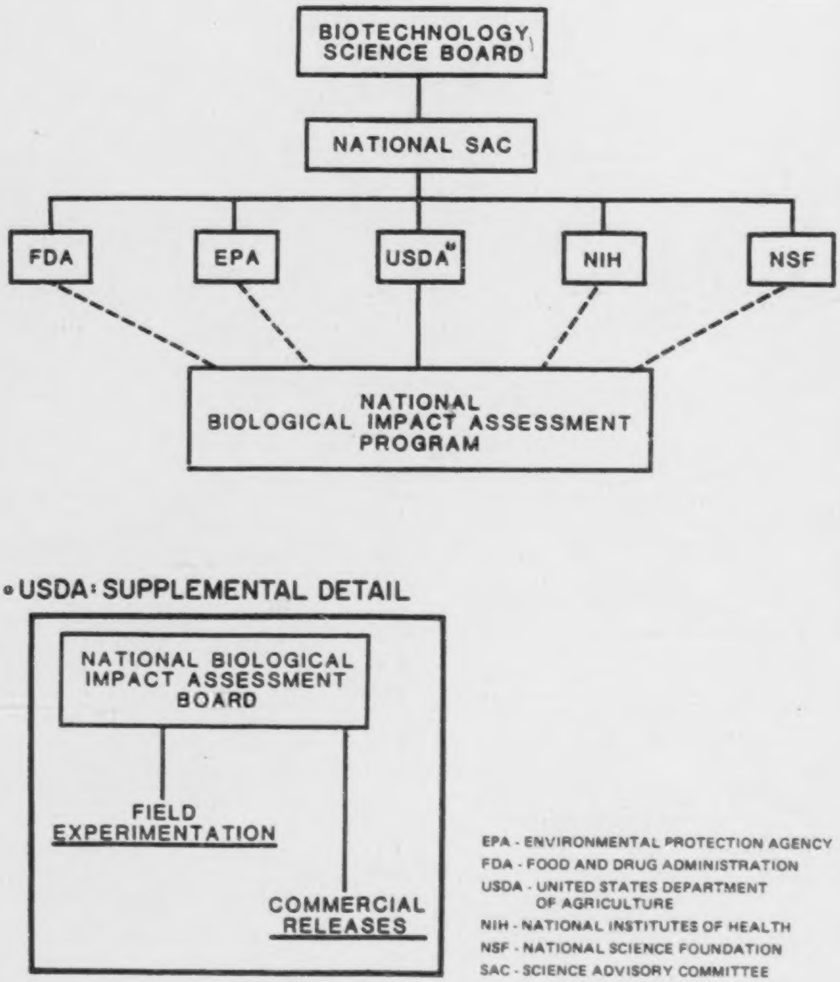
° USDA: SUPPLEMENTAL DETAIL



EPA - ENVIRONMENTAL PROTECTION AGENCY
FDA - FOOD AND DRUG ADMINISTRATION
USDA - UNITED STATES DEPARTMENT OF AGRICULTURE
NIH - NATIONAL INSTITUTES OF HEALTH
NSF - NATIONAL SCIENCE FOUNDATION
SAC - SCIENCE ADVISORY COMMITTEE

Figure 1. Diagram of the relationship between the National Biological Impact Assessment Program and the proposed Coordinated Framework for Regulation of Biotechnology (December 31, 1984, Federal Register Notice)

ORGANIZATIONAL RELATIONSHIP: NBIAP: OPTION 2


BIOTECHNOLOGY SCIENCE BOARD
NATIONAL SAC
FDA
EPA
USDA*
NIH
NSF
NATIONAL BIOLOGICAL IMPACT ASSESSMENT PROGRAM
*USDA: SUPPLEMENTAL DETAIL
NATIONAL BIOLOGICAL IMPACT ASSESSMENT BOARD
FIELD EXPERIMENTATION
COMMERCIAL RELEASES

EPA - ENVIRONMENTAL PROTECTION AGENCY
FDA - FOOD AND DRUG ADMINISTRATION
USDA - UNITED STATES DEPARTMENT OF AGRICULTURE
NIH - NATIONAL INSTITUTES OF HEALTH
NSF - NATIONAL SCIENCE FOUNDATION
SAC - SCIENCE ADVISORY COMMITTEE

Figure 2. Diagram of the relationship between the National Biological Impact Assessment Program and a single Science Advisory Committee.

This sequence of activities leads to the funding of approved r-DNA research proposals that have met all of the requirements of NBIAP for laboratory and related containment (Level 1) research.

Level 2. Special Contained Research

The following sequence is based on the assumption that an investigator or group of investigators has developed a biotechnological research product involving r-DNA, and field testing is appropriate. Field testing would involve a controlled release for further experimentation in natural or agricultural ecosystems. The goal of the test would be to determine the performance or specific properties of the research product in the environment. A generalized procedure under NBIAP for special contained research (controlled field release experimentation) follows:

A. Submission of the proposal to the SAES Director and/or other appropriate offices for review and approval.
B. Submission of the proposal to the EL-IBC or Cultivar Release Committee for evaluation of the proposal and determination that adequate procedures have been outlined for protection of the environment. Criteria and protocols developed at both the local and the national levels would be used.
C. Submission of the proposal to the appropriate institutional committees on radiation, animal safety and ethics, the human subjects review board and other required reviews.
D. Submission of the proposal to the NBIAP Board in those cases not requesting funding. Proposals requesting funds would be submitted to the appropriate funding agency. (The NBIAP board will develop criteria and protocols to judge each proposal for r-DNA field release experimentation.) Program subcommittees will evaluate individual proposals on a case-by-case basis.
E. In appropriate instances, identified by product, organism or intended use, referrals to another agency would be made.
F. The NBIAP Board will decide whether to allow the field release based on the recommendations of other agencies and NBIAP subcommittees.
G. The decision of the NBIAP Board would be communicated to the funding agency or the principal investigator.

At any point, review could be stopped and the proposal returned to the sponsor or the principal investigator for additional information. The only new national structure required is the NBIAP Board. Criteria established by the NBIAP Board to judge the merits and the potential environmental effects of various proposals would be in compliance with the goals of the National Environmental Policy Act (NEPA).

Level 3. Commercial and Other Non-experimental Release

Given approval at Levels 1 and 2, the product of the r-DNA research effort could be considered for release on a commercial or non-experimental scale. The following procedures would be used in obtaining approval for such a release. It is envisioned that this process would be a function of NBIAP.

A. The institution, agency or industry proposing the r-DNA product release would prepare a release request document which would include the following information:

1. A description of how the product was developed.
2. A statement of the performance of the product under laboratory, greenhouse and experimental field conditions. Emphasis would be placed on data which have assessed the potential impact of the proposed release on the environment.
3. Documentation that protocols established under Levels 1 and 2 were satisfied.
4. A description of the assessment program that will be used to evaluate potential effects of release on the environment. Specific releases might dictate the use of different systems of assessment. It would be incumbent on the organization proposing the release to provide a detailed description of the evaluation protocols to be used. When appropriate protocols are not available, the organization proposing the release would outline specific research to develop such protocols.

B. The release request document would be submitted to the NBIAP Board for evaluation and approval. In the case of SAES the release request document would be submitted to the EL-IBC or the Cultivar Release Committee. With approval at that point, the proposal would be forwarded to the NBIAP Board. If the release should be proposed by an institution other than a land-grant institution the release request document would be submitted to the SAES Director in the state in question who would forward it to the EL-IBC or Cultivar Release Committee at the land-grant university. With the SAES director's approval, it would be forwarded to the NBIAP Board.

If the release request was to be submitted by a state agency, that agency would submit the release request document to the SAES director. It would follow a path similar to that described above for institutions other than land-grant.

If the request for release was to be submitted by private industry, it would be submitted directly to the NBIAP Board.

C. After evaluating the proposed commercial or non-experimental release, NBIAP would approve the proposal, require more information or reject the proposal. The reasons for rejection would be provided to the applicant agency or institution in writing.

VII. Legal Issues Related to Release of r-DNA Products

Legal responsibility for releases into the environment must be considered by researchers and those who view, regulate and assess them. Regulatory laws must be followed on the federal, state and local levels, while legal rules governing liability for harm or injury must be considered at all levels of research, development and oversight. Within the common law -- or the legal rules derived from court decisions and social customs rather than from statutes -- the laws of negligence and strict liability have been developed in order to define standards for courts in determining the legal responsibility of people in relation to others in society. Many common law principles are set down in statutes and ordinances in order to delineate responsibilities more precisely. Federal laws allow agencies, such as EPA, FDA and USDA to control certain activities within their particular areas of jurisdiction and expertise. In the development of the plan for NBIAP, consideration has been given to the laws of liability which are summarized in Appendix C.

APPENDIX A
REGULATIONS AND PROTOCOL FOR INTRODUCTION AND RELEASE OF PARASITES, PREDATORS, WEED FEEDERS AND OTHER BENEFICIAL SPECIES FOR BIOLOGICAL CONTROL

State Agricultural Experiment Stations and their cooperators have been releasing biological control agents into the environment for many years. Rather highly structured protocols have been developed for this purpose, and they were developed with the central theme of protecting the environment against inadvertent releases and releases that had the potential to become pests. These protocols vary from institution to institution and state to state but in general they have a common fabric. The following information describes protocols and regulations used in the State of Florida for the release of biological control agents and other kinds of beneficial species. This statement is presented as an example of the type of protocols that exist for regulating and monitoring the release of biological controls. The following information could be used to develop a general protocol that would be used by NBIAP.

The Division of Plant Industry (DPI) of the Florida Department of Agriculture and Consumer Services has regulatory authority over the movement of insects and other biological control agents into and within the State. However, by agreement, there must be unanimous agreement among DPI, USDA-Agricultural Research Service (ARS) and the Institute of Food and Agricultural Sciences (IFAS) on the introduction of parasites, predators, weed feeders or other beneficial species proposed for use in biological control.

When an introduction is proposed, representatives of each agency review the case, and a decision is reached on the basis of their findings. The following information is required for the issuance of an importation permit: 1) purpose of importation, 2) name of natural enemy, 3) name of host species, 4) stage of development to be imported, 5) country and place of origin of material to be imported, 6) estimated number of organisms to be shipped and time of shipment, 7) method of shipment, 8) point of arrival and address of final destination, 9) packaging specifications, including escape-proof features, 10) local security measures to be used and 11) ultimate disposition of imported material.

The importation of beneficial species shall not involve entry into Florida of a) plants that are hosts of citrus canker, b) fruits or vegetables that serve as hosts of the Mediterranean fruit fly or related fruit flies from countries where such pests are known or believed to occur or c) hosts of injurious pests not known to occur in or to be widely distributed within the United States.

All shipments must clear through the Gainesville Quarantine Laboratory at the Doyle Conner Building (DPI). That laboratory is designed to provide maximum security against the escape of imported material (beneficial species, host material disease organisms or hyperparasites, etc. inadvertently accompanying the shipment). While in security, parasites and predators are screened for hyperparasites and parasites respectively. Only first generation eggs of introduced parasites and predators of reared pure cultures of the beneficial species are allowed to leave the quarantine facility, and then only if a thorough study has disclosed that their respective hosts do not include native species of beneficial organisms including other parasites or predators, crop species or other useful plants.

All plant material is screened for pathogens, and if found, associated beneficial organisms are screened for their ability to transmit the pathogen.

All material included with a shipment (plant material, soil, packaging, etc.) is destroyed or autoclaved before being removed from the Quarantine Laboratory.

Only authorized personnel are permitted in the laboratory, and they must follow prescribed clothing and procedural regulations upon entry and exit from the facility.

Having cleared quarantine, a beneficial species may be released for research outside of the quarantine facility or for propagation and release in the State. Such action is recorded by a USDA Biological Shipment Record-Non Quarantine to be completed and forwarded to the USDA offices in Beltsville, Maryland. The record contains information on the species shipped, shipper and receiver, type or organism (parasite, predator, weed feeder, competitor, etc.) and intended release or recolonization.

Formal regulations governing post release studies have not been developed. In practice, sometimes the consequences of releases are followed, as was done with Encarsia lahorensis released to control citrus whitefly. The efficacy of the parasite in controlling whitefly has been followed through an organized study. Earlier releases of parasites, such as Aphytis lepidosaphee (1958) and A. holoxanthes (1960) to control Florida red scale were not followed by organized studies of their efficacy, but Florida red scale has been eliminated as an economic pest since those releases.

APPENDIX B
INSTITUTE OF FOOD AND AGRICULTURAL SCIENCES
UNIVERSITY OF FLORIDA
POLICY OF STATEMENT GOVERNING RELEASE AND INTRODUCTION OF PLANT MATERIAL
DECEMBER 1981

The Institute of Food and Agricultural Sciences (IFAS) has the responsibility for developing and releasing new cultivars of field, forage, vegetable, fruit, ornamental and forest crops to support agriculture, horticulture and natural resources development in Florida where such activity is consistent with current needs and policy. The policy and procedure statements outlined in this document are intended to provide guidelines for the release of various classes of plant material developed by IFAS or originating through cooperative efforts with other state, federal or private organizations.

I. Cultivar Release Committee

The IFAS Cultivar Release Committee consists of Chairpersons of the Departments of Agronomy, Fruit Crops, Ornamental Horticulture, Vegetable Crops; the Director of the School of Forest Resources and Conservation; the Assistant Dean for Extension, Agricultural Programs; a representative of the Florida Foundation Seed Producers, Inc.; a representative of the Florida Department of Agriculture and Consumer Services; a research center director appointed by the Dean for Research; and the Dean for Research who serves as Chairperson. The Committee meets at least quarterly to consider requests (made by Cultivar Release Advisory Committees) for the release of new plant materials, i.e., cultivars, inbred lines, clones, hybrids or germplasm. The Cultivar Release Committee:

A. Is responsible for approving the composition of Cultivar Release Advisory Committees;

B. Approves the release of foundation stock of new plant materials developed by IFAS, including material provided to IFAS, when sufficiently evaluated;

C. Approves stock increases and increase procedures for planting materials prior to release;

D. Approves the release of cultivars and other new plant materials;

E. Sets the release date of cultivars and other new plant materials;

F. Reviews and approves authorship of cultivar release circulars;

G. Approves the names of cultivars and other new plant materials, using as a guide the International Code of Nomenclature for Cultivated Plants;

H. Forwards applications and documentation as may be required to the University of Florida Patent Subcommittee which shall make a determination as to protection to be sought by the University prior to final action by the Release Committee;

I. Receives and reviews minority reports associated with the consideration of any candidate cultivars.

II. Cultivar Release Advisory Committee

A Cultivar Release Advisory Committee is appointed for each potential cultivar or new plant material release. The Cultivar Release Advisory Committee:

A. Evaluates proposed releases regarding their intended purpose. (This Committee shall take whatever action is needed to carry out this function, including on-site inspection and evaluation.)

B. Reviews and evaluates performance data accumulated by developers and cooperators. (During the evaluation period of at least one crop cycle, the Committee shall act in an advisory capacity to developers.) If at the end of the evaluation period three-fourths of the voting members approve, the chairperson of the Advisory Committee shall notify the IFAS Cultivar Release Committee that the cultivar should be considered for release.

C. Submits drafts of release circulars with recommended cultivar names and cultivar descriptions prepared by developers.

D. Suggests the authorship of release circulars.

E. After the above procedures are completed, the Advisory Committee shall act as deemed necessary to assist members of the IFAS Cultivar Release Committee in their deliberations.

Voting members of the Cultivar Release Advisory Committee consist of a minimum of five individuals capable of evaluating proposed releases with regard to their intended purposes. The composition of the Committee is recommended by the appropriate commodity chairperson to the IFAS Cultivar Release Committee for approval and appointment. At least two of the members are affiliated with departments other than that of the department commodity chairperson. Non-voting members of the Cultivar Release Advisory Committee consist of the chairperson of the appropriate commodity department, who serves as chairperson of the Committee, a representative of Florida Foundation Seed Producers, Inc., the appropriate Center Director, and the developers. Developers are those who work in cooperation with breeders for a significant period of time and not persons only involved in the final evaluation.

III. Chronological Procedures for Cultivar Release

A. Developers notify the chairperson of the appropriate commodity department, either directly or through the center director if located at a research center, of intent to recommend a new or improved cultivar for consideration for release. The commodity chairperson then recommends a Cultivar Release Advisory Committee to the IFAS Cultivar Release Committee for approval and subsequent appointment.

B. The Cultivar Release Advisory Committee is appointed at least one growing season before anticipated releases. Committee members become acquainted with potential releases with respect to their intended purposes, including review under production and evaluation conditions. The Committee meets as often as necessary but at least once quarterly. The Committee reviews data, advises developers and makes recommendations concerning potential cultivars.

C. The chairperson of the IFAS Cultivar Release Committee is notified when the Advisory Committee determines that the potential cultivar should be considered for release. Notification is accompanied by documentation, including a draft of the release circular with an official cultivar description prepared by developers and the Advisory Committee, supporting evidence for release.

D. The IFAS Cultivar Release Committee chairperson makes available to members of the Committee the release documentation from the Advisory Committee and places the release of potential cultivars on the agenda of the next scheduled meeting. Developers meet with the Committee to answer appropriate questions. Others may be called upon by the Cultivar Release Committee to answer questions concerning this cultivar.

E. The IFAS Cultivar Release Committee makes the decision concerning the release. Consideration is given to production of propagation material in sufficient quantities to supply demand and ensure future production. A quorum consists of two-thirds of the full Committee. Release is denied if there is more than one dissenting vote. In the event of denial, the consideration is referred back, with comments, to the Cultivar Release Advisory Committee. Cultivars rejected for release may be resubmitted with additional documentation.

F. The IFAS Cultivar Release Committee assists the Florida Foundation Seed Producers, Inc. (when applicable) in determining propagation methods, the maintenance of breeder and foundation stock, availability of cultivars and preparation of publicity materials. The advanced increase of the propagules of especially promising lines is possible with the concurrence of the Cultivar Release Committee and the Florida Foundation Seed Producers, Inc.

G. Final approval of the cultivar name rests with the IFAS Cultivar Release Committee. Names shall conform with the International Code of Nomenclature for Cultivated Plants.

H. Following the approval for release by the Cultivar Release Committee, developers are responsible to publish formally cultivar descriptions in appropriate journals.

I. Materials denied release as cultivars shall, at the developer's request, be considered for germplasm release.

IV. Procedures for Germplasm Release

A. Developers recommend releases of germplasm to the department chairpersons, who then make recommendations to the Chairperson of the Cultivar Release Committee.

B. A Germplasm Release Advisory Committee is then appointed by the Cultivar Release Committee. The Advisory Committee reviews available data and makes recommendations to the IFAS Cultivar Release Committee. If release is recommended by the Cultivar Release Committee, then the Advisory Committee forwards appropriate documentation, including a brief description of the germplasm, to the IFAS Cultivar Release Committee.

C. The IFAS Cultivar Release Committee considers all recommendations of the Advisory Committee and renders final determinations.

V. Relations with Florida Foundation Seed Producers, Inc.

The Florida Foundation Seed Producers, Inc. serves as the conduit or mechanism whereby cultivars released by the Florida Agricultural Experiment Stations are made available to industry. The purpose of the Florida Foundation Seed Producers, Inc. is:

1. To insure foundation seed stocks of the best known varieties adaptable to Florida climate and soils in adequate quantities and at reasonable prices are available annually to Florida farmers and producers of crop seed and nursery stock.

2. To cooperate with the Agricultural Experiment Station of the University of Florida in making available to the farmers of Florida new and improved varieties of crop seed; to obtain such improved seed stocks by purchase, barter, lease or gift; to propagate and increase the same through any agency and particularly by contracting with producers and institutions; and to disseminate such increased stock to its members and others.

The Manager of Florida Foundation Seed Producers, Inc. is a non-voting member of IFAS Cultivar Release Advisory Committees. Also the IFAS Deans for Research and Extension of the University of Florida serve as ex-officio members of the Foundation's Board of Directors.

VI. Joint Releases

Joint release efforts have been especially productive in the past; they reflect the high degree of cooperation between IFAS and agencies such as USDA, and it is the intent of this policy to encourage joint development and release of cultivars. When an industry, state or federal agency is directly involved in the development of new plant material, a joint release between IFAS and the cooperating organization(s) shall be made, subject to approval of the parties involved. The release of information shall be through a joint agreement between IFAS and the cooperating organization(s).

Cultivars to be released by another state or agency in accordance with their own policies can be released jointly with Florida, even though Florida did not play a major role in the development of such cultivars. The decision to release such cultivars jointly shall be made by the Cultivar Release Committee upon receipt of a recommendation from a specially constituted Cultivar Release Advisory Committee or after consultation with the concerned breeders and evaluators, whichever is appropriate.

VII. Guidelines for Release of Cultivars within Commodity Areas

A. General

A new cultivar shall have a high potential for making a significant contribution to Florida agriculture. This is often accomplished by increasing the yield potential for the crop, but it may also be accomplished by reducing production hazards, increasing management efficiency, improving consumer and nutritional quality or by other means. New food or feed cultivars shall be "generally recognized as safe substances" as stated in the Code of Federal Regulations 21 CFR Part 170.30(f)(2). Affirmative answers to four questions relative to the proposed cultivar are important: (1) Do advantages over existing cultivars significantly outweigh disadvantages? (2) Is it economically feasible for growers to use the new cultivars? (3) Is there strong likelihood that growers will actually use the new cultivar? (4) Can assurances be given that the new cultivar will not become a noxious weed?

B. Commodity Areas

I. Horticultural Crops

A. Guidelines for evaluating horticultural crops shall include:

1. When possible, cultivar evaluation using replicated trials with standard cultivars for a minimum of three cropping cycles prior to submission for state testing.

2. Cultivars propagatable in such a way to maintain their identity.

3. That fruit cultivars be self-fruitful or that a suitable pollinator be available.

4. That, when possible, developers provide comparison cultivars for testing.

5. That developers provide data sheets showing characteristics to be observed and data to be collected including timing of data collection.

6. That developers provide available cultural data to ensure maximum performance of the cultivar.

7. That developers assist those responsible for the evaluation of the cultivar in the experimental plot design and be responsible for statistical analyses of data collected from the testing locations.

B. These guidelines may be revised periodically by the Cultivar Release Committee. Exceptions to the stated policy will only be acknowledged upon review and action by the Advisory Committee.

2. Agronomic Crops

A. Guidelines for evaluating agronomic row crops shall include:

1. Performance data from a minimum of six environments, which usually will include replicate trials for at least two years at two locations.

2. Acceptable chemical or other quality data as appropriate for the species.

3. Appropriate testing to demonstrate small advantages with low heritabilities.

4. Data describing limits of acceptable adaptation where needed. (In some cases, these limits can be inferred from existing data with acceptable accuracy.)

5. Subjection of potential cultivars, where practicable, to production hazards likely to be encountered in actual farm situations before being recommended for release. (Resulting data shall be of a nature to provide reasonable assurance that the release will be a credit to the breeder and to IFAS.)

B. Guidelines for evaluating forage crops shall include:

1. The criteria specified under Section 2. A.

2. Data on forage response to grazing such as yield, persistence and resistance to plant pests and disease.

3. Data on animal responses such as intake, palatability, toxicity and overall performance.

4. Comparison of candidate cultivars with commercially accepted cultivars.

C. These guidelines may be revised periodically by the cultivar release committee. Exceptions to the stated policy will only be acknowledged upon review and action by the advisory committee.

3. Forestry Crops

   A. Guidelines for evaluating forestry crops shall include:

      1. Performance data from a minimum of three representative field trials. (For growth assessments, at least two sites shall be included; pest resistance evaluations shall be based on trials established over at least two different years.)

      2. Inclusion of one or more check seed lots in each field trial. (A check seed lot shall characterize typical planting stock used in the planting region.)

      3. Sufficient length of the evaluation period. (Growth of long-term crops, such as pulpwood and sawtimber, shall be monitored for one-half the duration of the rotation. Growth performance of short-term crops (e.g., Christmas trees, woody biomass) shall be observed over a full rotation. Other traits, such as certain types of pest resistance, can be evaluated in shorter time periods if juvenile and mature performances are strongly correlated.)

      4. Maintenance of minimum standards for traits other than those not specifically improved. (Trees developed for greater growth shall be average or above for resistance to pests common to the planting region; pest-resistant trees shall have growth rates at least equal to those of unimproved stock.)

   B. Guidelines for production of planting stock shall include:

      1. Maintenance of adequate genetic composition in bulk seed from multi-genotype seed orchards. (Clonal and seedling seed orchards shall have sufficient isolation from contaminant sources of pollen and shall be composed of at least 25 genotypes well distributed in the orchard.)

      2. Insurance of purity of single, or limited number of, genotypes from specialty orchards. (Such orchards shall be isolated from contaminant pollens, and compatibility of flowering of orchard trees shall be documented.)

      3. Continuity for production of vegetative propagules. (Sources of vegetatively derived stock shall be observed to maintain desirable characteristics for the period of utilization.)

   C. These guidelines may be revised periodically by the Cultivar Release Committee. Exceptions to the stated policy will only be acknowledged upon review and action by the Advisory Committee.

APPENDIX C
LEGAL CONSIDERATIONS OF THE RELEASES OF RECOMBINANT DNA ORGANISMS INTO THE ENVIRONMENT

Regulatory Structure

The release or movement of biological organisms is controlled by several federal agencies through a variety of statutory rules. Research in r-DNA is reviewed by the NIH-RAC. Federally funded r-DNA research requires compliance with the NIH r-DNA Guidelines, and all other programs may comply voluntarily. This review covers research in contained areas, e.g. laboratories. The United States Department of Agriculture regulates the movement of biological products and organisms through the plant and animal quarantine laws and the Virus-Serum-Toxin Act. The Environmental Protection Agency has authority under the Toxic Substances Control Act (TSCA) to address the risks posed by exposure to "chemical substances." Since "chemical substances" has been interpreted broadly by EPA, nucleic acids as well as living organisms are considered to be subject to EPA regulation under TSCA. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) empowers EPA to determine the control and safety of pesticides. The Food and Drug Administration regulates food additives, human drugs, biologics and medical devices through the Public Health Service Act. While FDA's activities are not recognized as dealing with releases into the environment, environmental assessments are normally prepared for new products or new uses of existing products. The Occupational Safety and Health Administration (OSHA) is concerned mainly with safety of workers. The present United States regulatory structure is concerned chiefly with large-scale and commercial applications. Experimental and small-scale uses are subject to exemptions from regulation. The introduction of modern technologies has prompted the call for greater oversight of laboratory work and basic research, especially in the area of r-DNA.

Local governing bodies might establish regulatory restraints as well, where they are not prohibited by preemptive federal legislation. Early in the development of r-DNA technology several state and municipal governments (Cambridge and Amherst, Massachusetts; Princeton, New Jersey; Berkeley, California; and the states of Maryland and New York) enacted legislation to control the application of this new innovative science. In general, these statutes require local review of research proposals and compliance with the NIH r-DNA Guidelines.

Compliance with regulatory constraints is incumbent upon the individuals conducting the regulated activity, unless the statute places the burden on the regulatory agency. Failure to comply with regulations can result in liability to individual researchers and technicians or their employer. Noncompliance by researchers or technicians could be imputed to NBIAP bodies where the NBIAP has continuing oversight of a project. The NBIAP also might incur common law liability resulting from harm or injury caused by an experiment that it reviews and/or assesses.

Common Law

The laws of negligence and strict liability are the most important source of liability which might result from the release of a biological organism that causes harm or injury. Standards of negligence and strict liability can be determined by statute, but liability also can be established with reference to an extensive body of common law. Liability for negligence is demonstrated when a generally recognized duty is breached, and that breach causes harm or injury to another. That duty involves the relationship between the conduct of the individual to the standard of a reasonable person in avoiding conduct which places others in danger of harm or injury. Under a strict liability theory, liability is established without regard to the reasonable standard of care when an abnormally dangerous instrumentality or condition causes harm or injury to another. Common law principles of negligence and strict liability have been developed in order to provide relief to those who have been harmed or injured by unreasonably dangerous activities or conditions.

In a negligence suit involving the release of a biological organism, an important aspect is the proof of the appropriate standard of care. Standard guidelines and protocols for research or experimentation procedures are reliable measures for the establishment of standards of care. Where r-DNA organisms are involved, compliance with the NIH r-DNA Guidelines would weigh heavily in favor of a reasonable standard of care. Any guidelines or protocols established by the NBIAP also would be useful in determining reasonable research procedures. If a court determines that a reasonable standard of care has been upheld, there can be no negligence.

Where a negligence action cannot be maintained, liability still may be established if a strict liability standard is employed. The law of strict liability was developed as a social policy to place responsibility upon those engaged in unusually dangerous activities, even when utmost caution and care are used. In order to show strict liability, one must prove that the particular activity is abnormally dangerous in the particular location. Strict liability might be applied to modern biotechnologies although the legal issue has not been judicially resolved.

Whether the court action is for negligence or for strict liability, in order to prevail, one must show that the activity actually caused ultimate harm or injury. This is called proximate causes or legal cause. Liability only can be established where there is causation in fact. Proof of proximate cause becomes complicated when there is more than one cause of injury. Courts then ask: Would the injury still have resulted had the activity complained of not occurred? Could the injury have resulted had the activity complained of been the only cause? To establish proximate cause, the activity must be a material and substantial factor in causing harm or injury.

Legal liability depends upon many factors and conditions. Different circumstances or parties may result in shifted liabilities. The facts of each case must be viewed from the vantage point of the reasonable person, who provides the ultimate standard of guidance. In assessing liability, concepts relating to nuisance also must be considered seriously.

APPENDIX B

USDA

Biotechnology Research

($ in Millions)

	FY 1983	FY 1984	FY 1985	FY 1986 Budget
ARS				
Plant Productivity	$5.9	$6.9	$10.0	$10.8
Albany Gene Expression Center	(0)	(0)	(2.0)	(2.9)
Animal Productivity	6.6	6.8	8.8	8.6
Soil & Water Conservation	1.0	1.1	0.2	0.2
Commodity Conversion and Delivery	0.3	0.6	7.2	7.2
Human Nutrition	- -	- -	0.1	0.1
ARS Total	13.8	15.4	26.4	26.9
CSRS				
Hatch Act	8.9	9.1	12.2	12.2
Special Research Grants	1.6	3.5	3.4	- -
Competitive Research Grants	8.3	9.0	29.5	29.5
All other	1.0	1.0	1.0	0.4
CSRS Total	19.8	22.6	46.1	42.1
Forest Service				
Intramural	0.4	1.1	1.0	0.9
Competitive Grants	- -	- -	1.6	- -
FS Total	0.4	1.1	2.6	0.9
USDA Total	34.0	39.1	75.1	69.9

USDA is placing increased emphasis on use of the new biotechnologies in forestry and agricultural research. Biotechnology is broadly defined to include the technologies of gene transfer (genetic engineering), cell and tissue cultures (asexual propagation), protoplast fusion (asexual genetic recombination from diverse species), and embryo manipulation and transfer.

These programs expanded significantly in FY 1985. This emphasis will be maintained in FY 1986 with two exceptions: (1) the new program of Forestry Competitive Grants funded through an FY 1985 Congressional add-on is proposed for termination, (2) the $28.5 million CSRS Special Research Grants program, of which a small portion goes to biotechnology research, is proposed for termination.

APPENDIX C

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

JUL 5 1985

Ms. Cheryl P. Coodley, Staff Director
Subcommittee on Investigations and Oversight
Room 822 House Annex #1
Washington, D.C. 20515

Dear Ms. Coodley:

I am pleased to respond to you as requested in Chairman Harold L. Volkmer's letter to me on June 17, 1985. Our response to the Chairman's two questions are attached with this letter.

We appreciate this additional opportunity to add important information to your hearing record of April 16, 1985, on Biotechnology and Agriculture.

Sincerely,

Orville G. Bentley
ORVILLE G. BENTLEY
Assistant Secretary
Science and Education

Attachment

Attachment - Letter to Cheryl F. Coodley, Staff Director
July 2, 1985

1. During the hearing, much of the discussion centered around the Department of Agriculture's biotechnology research program. One area, instrumentation at land-grant universities, was not adequately covered. Does the Department direct any funds to the land-grant universities for the purchase of biotechnology research instruments? If so, how much? Is the supply of biotechnology research instruments at land-grant universities adequate? In general, are the biotechnology research instruments at land-grant universities up to date?

> The Department does not direct funds to the land-grant universities for purchase of biotechnology research instruments. We allow the purchase or acquisition of instrumentation as one of the costs of conducting research on a given project. Collectively, this is a small amount, averaging approximately 2% of the Department's funding of biotechnology research in the land-grant universities.
>
> The instrumentation for biotechnology research at land-grant institutions is not adequate. The November, 1983, meeting of the National Association of State Universities and Land Grant Colleges, Division of Agriculture, the Committee on Biotechnology took formal action to design the documentation of the current status and the projected needs over time. This design study was completed and it has recently been implemented through an Evaluation Study entitled, Analysis of Instrumentation Needs in Biotechnology for the State Agricultural Experiment Stations, by my office. Completion of this study this year will provide sound documentation of current and projected needs.

2. During the hearing, several witnesses testified that there is a need for a strong research program in the basic sciences of plant biotechnology. What is the level of the Department's support for research in plant biochemistry, plant physiology, and molecular genetics? What are the Department's long-range plans in each of these fields?

> The level of the Department's support for plant biochemistry, plant physiology, and molecular genetics in support of biotechnology research is approximately 42 million dollars. These fields are pursued through many different disciplines and special areas of scientific expertise. It is our long-range plan to increase support in these fields and disciplines and do so in a balanced fashion i.e. as emerging knowledge dictates new techniques, new boundaries, and therefore new opportunities. We believe this will prove most effective in bringing the benefits of biotechnology to our nation.

APPENDIX D

Office of the Deputy Vice President

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Cheryl F. Coodley
Staff Director
Subcommittee on Investigations and Oversight
Room 822 House Annex #1
Washington, DC 20515

Dear Ms. Coodley:

I am responding to the June 17 letter from Representative Harold Volkmer in which he asked me a question as follow-up to the April 16 hearing on Biotechnology and Agriculture.

My response to the question is as follows:

> We (the state Agricultural Experiment Station System and USDA) have not enjoyed the support relative to the biomedical sciences to dedicate the basic research. There has not been sufficient federal support provided for agricultural research broadly such that basic research in agricultural biotechnology could be given adequate attention. I would not lay the blame "...at the feet of the USDA..." because the USDA has to address the broad array of agricultural research needs for basic science to the application of technology via new plant varieties, animal breeds and various products and processes. Rather, I'd suggest that Congress does not recognize the need to make an adequate public investment in agricultural research at the federal level.
>
> The plant cell side of biotechnology research has not had the attention that the animal cell area has had, the latter having benefited from research support through NIH. The FY85 increase in the USDA Competitive Grants Program was a good start but much additional support will be needed to realize in agriculture the advantages which are possible with plants and microorganisms as a result of biotechnology.

> While I believe your question about an adequate level of support should be addressed broadly to the land-grant university system and specifically to the Budget Committee of the Division of Agriculture of NASULGC, I'd suggest that an additional $30-40 million annually invested in plant sciences research broadly and into the microbiological aspects of plant science agriculture specifically would go a long way towards reaching an appropriate and necessary level of investment. I cannot overemphasize enough the need for an improved federal investment in basic plant science research if we are to keep U.S. agriculture competitive in today's international economy.

Thank you for providing me the opportunity to make additional input. If you have any further questions or wish additional information, I'd be happy to respond.

Sincerely,

Richard J. Sauer

Richard J. Sauer
Deputy Vice President

RJS/lm

APPENDIX E

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CONSULTANTS

July 8, 1985

Mr. Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight
822 House Annex #1
Washington, D.C. 20515

Dear Mr. Volkmer:

This letter is to go on the record with respect to the April 17, 1985 Subcommittee on Investigations & Oversight hearing, held in Washington, D.C., during which our employee, Dr. George Kidd, testified.

There are some elements of Dr. Kidd's testimony with which the Company does not agree.

Thank you.

Yours very truly,

L. WILLIAM TEWELES & CO.

L. William Teweles

LWT:na